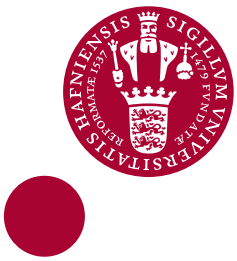

Ethical decision-making

Practical guidance & toolkits on ethical decision-making and considerations for field projects targeting dogs and cats

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ACC&D
Alliance for Contraception in CATS & DOGS

ETHICAL **decision-making**

Practical guidance & toolkits on ethical decision-making and considerations for field projects targeting dogs and cats

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INTRODUCTION

This resource provides guidance on the ethical considerations associated with field projects with cats and dogs. In doing so, it aims to aid organizations and individuals conducting this work to ensure that ethical issues receive as much focus as the many other considerations involved in a successful project.

For the purpose of this resource, we define "field" as outside a laboratory; this can range from clinical studies through a veterinary office to outreach activities in a local neighborhood to projects in another country.

"Projects" are also broadly defined. We view them as any intervention that involves a novel or unknown element, with the purpose of benefiting the animals who take part in the project and/or future populations of animals. Consequently, "projects" include traditional research, with or without university affiliation—examples are research and testing of new pharmaceuticals or non-surgical technologies with owned or free-roaming animals outside a laboratory. They *also* include common animal welfare interventions, such as a Trap-Neuter-Vaccinate-Return (TNVR) project, an initiative to increase spay/neuter among owned pets, or a street dog population management and rabies control campaign. It would be easy to view these interventions as known entities, but the reality is that *all* of them involve unknowns and novel elements—even as simple as working in a new community—that could affect outcomes, stakeholders, and animal welfare. They should therefore be approached with an open mind—i.e., as the testing of an idea or hypothesis—with data collected to allow the hypothesis to be objectively tested, and with full consideration given to the ethical implications of all elements of the project.

This resource is focused on the well-being of both animals *and* their humans. Although field projects are commonly undertaken with the admirable intention that animals (individuals, the target population, or future populations) and/or humans benefit, they have the potential to cause harm. This harm can manifest not only for the cats and dogs who are targets of the project, but also for other stakeholders, both human and non-human. Those who design and implement projects therefore have an ethical responsibility to ensure that all actions are justified, to do their utmost to ensure that work is humane for **dogs or cats**, and to consider both **owners/guardians** and the broader **communities** in which the animals live. This approach falls under the "One Welfare" paradigm, which highlights the interconnections between the well-being of animals, humans, and the environment and serves as a platform to improve both human *and* animal welfare (One Welfare, 2018; Pinillos et al., 2016).

The idea for this resource was inspired by two research initiatives led by the Alliance for Contraception in Cats & Dogs (ACC&D). One involved a promising non-surgical contraceptive vaccine for free-roaming cats, and the other involved a novel method to identify free-roaming animals who are non-surgically sterilized or vaccinated against rabies. The former project took place in a facility custom designed to simulate a "real-world" environment for free-roaming cats, and the latter in conjunction with a rabies vaccination campaign for owned and community dogs in rural Kenya.

The process of developing and implementing these projects raised ethical questions, yet guidance on the ethical aspects of animal research outside a traditional laboratory was very

limited (Tasker et al., 2018). In short, the projects did not fall clearly within the scope of an Institutional Animal Care and Use Committee (IACUC), a framework for compliance with federal policies, guidelines, and principles related to the use of animals in research, teaching, and testing in the U.S. The fact that the research took place in communities, and in some instances with owned pets, added a clear human element to ethical decision-making. Meanwhile, an Institutional Review Board (IRB) is responsible for protecting the rights and welfare of human research subjects in the U.S., with no application to animals. Components of each ethical review framework were relevant to ACC&D's research, but neither was wholly applicable. The effect is gaps in protections for owned pets enrolled in research outside of a laboratory setting, community or loosely owned animals without clearly identifiable owners, and people in communities where animals are the primary research target but where there are impacts on human populations, too. These limitations to oversight and protections hold true for many other countries' ethical review structures, as well. We wanted something that would help ACC&D proactively address ethical questions for its future projects, as well as to serve the broader animal welfare and veterinary research communities.

In response, ACC&D convened experts at a Think Tank entitled "Ethical Decision-Making in Innovation for Animal Welfare." The meeting was designed to explore the appropriateness of existing approaches, to identify gaps in literature, and to address how gaps might be filled for people and organizations working in the field. Think Tank participants recommended the creation of this document and its associated toolkits to aid practical ethical decision-making for projects targeting dogs or cats.

WHO IS THIS RESOURCE FOR?

We believe that this guidance document and associated toolkits can offer value to multiple audiences:

- **Organizations that are conducting research or field trials while exempt from institutional ethical review.** In some countries, academic institutions and government agencies are required to submit proposed research involving animals and people for ethical review. Other entities, particularly non-governmental organizations, are not. Although formal, external ethical review is not required of all organizations, we believe that all organizations should nonetheless go through the steps of ethical review, even if it is an internal or informal procedure.
- **Organizations implementing novel, non-traditional field projects.** There is presently no requirement for ethical review for innovation, such as a new approach to animal birth control (ABC) or catch-neuter-vaccinate-release (CNVR) for community dogs, or a new method of determining which cats are suitable for adoption. Such projects are exciting due to their potential to advance animal welfare by providing more effective, humane, and/or cost-effective alternatives to current practices. However, innovation contains unknowns and risks to stakeholders, both animal targets and the broader community. Even when projects or innovations do not constitute traditional "research," their impacts can warrant ethical review and justification.
- **Entities whose research is presently required to undergo formal ethical review, as well as the bodies that are tasked with reviewing this research.** Current ethical review practices may contain some gaps, discussed below, which this document aims to help fill. We hope that these resources will permit more robust and

expansive consideration of research that simultaneously impacts animals *and* humans in both obvious and subtle ways.

- **Advocates, such as NGOs, that are trying to influence welfare conditions in field projects or to shape animal welfare policies.** These resources can help them assess existing work and push for improvements where needed.
- **Funders.** Many funders encourage innovation—a great thing!—but innovation can be met with ethical challenges and even risk to the populations it seeks to benefit. Funders are in a unique and valuable position to prompt potential grant recipients to address the ethical implications of their proposed projects as part of the grant application process.

These audiences are very broad, especially in combination. Not every component of this guidance document and associated toolkits will be relevant to every audience. We encourage you to focus on the material that is most applicable to your areas of focus and contexts of your projects.

HOW TO USE THIS RESOURCE

This guidance document offers a synopsis of ethical challenges and considerations that are part of field projects with companion animals, be it an initiative intended to directly help dogs and/or cats, or research and data collection to advance animal welfare or veterinary medicine.

The document is intended to introduce the topic of ethical decision-making and help you identify the specific topics that are most relevant to your work.[1]

These specific topics have complementary toolkits, which are summarized and hyperlinked in the guidance document. Each toolkit delves into topics at a deeper level than this guidance document, offering in-depth discussion, practical guidance and useful tools, relevant issues to consider, and case projects to bring to life ethical challenges that organizations have faced.

Navigating the document

Use the colorful, interactive tabs along the right pages to navigate the main sections of this document.

Gold hyperlinks connect directly to content within this document.

To return to the previous viewed page, click the "back" arrow icon at the top of each page.

Blue hyperlinks within the text connect to external references and online resources.

Citing this publication

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1 This resource is not intended to replace any legally mandated ethical review process or procedures. It is intended to provide additional information and resources for those who are undergoing a formal ethical review process, and to provide guidance for those implementing projects that are not subject to institutional ethical review, but where consideration of ethical implications is warranted.


BACK

GUIDANCE DOCUMENT

SECTION CONTENTS

UNDERLYING ETHICAL PRINCIPLES

At its core, ethics encompasses the moral principles that guide a person's views of right or wrong and their subsequent behavior (Rollin, 2006). Entities such as institutions or NGOs may also strive to operate based upon defined ethical principles. Ethical decision-making comes into play when facing choices about what course of action ought to be taken, either in a particular situation or as a matter of policy. A variety of influences, including personal, social, and cultural, can shape the ethical perspectives of individual persons, institutions, and organizations, plus the decisions that result.

Ethics is also an academic discipline, a branch of philosophy that examines the basis of moral principles that guide human conduct (Gensler, 2017). Within philosophy, different "schools" of ethical thinking have developed that underpin ethical decision-making. These schools go way back in the history of Western philosophy. In the 1970s, similar schools, or ethical perspectives, have emerged within the field of animal ethics (for an overview, see Palmer & Sandøe, 2018). These schools of thought are not only based on different principles; they will also in many cases give conflicting verdicts about what is an acceptable way to act. For example, use of animals in potentially painful but vital biomedical research (e.g., aimed at treating emerging diseases like *Ebola*) may be accepted from a utilitarian but be rejected from an animal rights ethical perspective.

To learn more about common ethical views relating to animals, and specifically to pinpoint your personal ethical views, we recommend visiting the online interactive learning tool Animal Ethics Dilemma.

The kind of ethical conflict described above is not simply a theoretical possibility. Individuals, institutions, and organizations hold different ethical views regarding animals, which can shape views of when and how to intervene with and/or "use" animals. A recent paper (Lund et al., 2019) documents four distinct and potentially conflicting animal ethics orientations among citizens of a Western European country: animal rights, anthropocentrism, animal protection, and utilitarianism.

At one end of the spectrum, the anthropocentric orientation stresses that humans are at the center of the moral universe. At the other end of the spectrum, the animal rights orientation claims that sentient animals are entitled to the same rights as humans. The animal protection orientation is interpreted as a mainstream sentiment emphasizing that the welfare of animals is important in its own right, and that animals must be treated humanely and in a manner that does not cause unnecessary suffering. Utilitarianism offers a more cynical take on animal welfare: all forms of animal use are in principle acceptable as long as the human benefits outweigh the risks for the animals involved. While the animal protection orientation was the most strongly supported among the European cohort studied in the research, there was a large variation, and all three remaining orientations also had a sizeable uptake.

There is every reason to expect similar findings if this project were undertaken elsewhere in the world. The implication is that some forms of animal treatment and animal use will remain controversial. Examples include raising and slaughtering animals for food, lethal

methods for managing so-called "surplus" animals, and the use of animals in potentially painful biomedical research.

However, other forms of treatment and use of animals might yield widespread—if not uniform—agreement. For example, when it comes to managing the health and reproduction of feral or free-roaming dogs and cats, positive outcomes for both animal welfare and the protection of vital human interests often seem to go hand-in-hand. Successful, humane dog and cat population control may have both the effect that fewer animals will suffer, and at the same time cause less of a health risk to humans living in the same area. Thus both adherents of ethical views focusing on protecting human interests and adherents of views focusing on animal protection and animal rights may be able to find common ground when it comes to defining policies around managing and/or studying the health and reproduction of dogs and cats.

The current document is focused on defining a policy of ethical review preceding field projects involving dogs and cats in field contexts, including those who are unowned, as well as those who have **owners or guardians**. Some of these projects are intended to directly benefit the target populations of animals; others are designed to benefit other populations. Humans (owners, guardians) and communities will nearly always be affected in some way. As we design projects, it is important to consider ethical principles as they relate to both the animals and humans who are affected.

ETHICAL REVIEW

ETHICAL REVIEW TOOLKIT

What is an ethical review?

By convention, "ethical review" is a systematic process to evaluate projects with or on humans or animals prior to their start. At its core, ethical review is meant to protect the interests of participants. It commonly explores potential harms and benefits for all participants and stakeholders, and it states mitigating factors to minimize harms where they are identified. To do this, ethical reviews require a somewhat pessimistic approach to identify potential harms, and a realistic approach to both calculate the risk of those harms and develop effective mitigating measures when needed. At the same time, however, the process of ethical review should seek to maximize the chance of achieving potential benefits and offer a realistic approach to attaining them.

Ethical review, often called institutional ethical review, is mandated for some projects because of the nature of the research, the effect on animals or humans, the context or location of the work, and/or the participating partners. Legal or regulatory requirements for ethical review vary and should be established as part of the planning process for any project.

Mandated institutional ethical review, as described above, is performed by formalized ethical review bodies. This is a panel of individuals with relevant expertise who provide

review services and guidance on the ethical acceptability of research on humans or animals (see Jacobs, 2010; Jennings & Smith, 2015; RSPCA & LASA, 2015). Ethical review bodies may have different names and tasks depending on where they are based, the research they review, their level of authority, the relevant regulatory bodies, and any other prescribed duties that are specified. Some examples of ethical review bodies include Animal Welfare and Ethical Review Bodies (AWERB), Ethics Committees (EC) or Research Ethics Committees (REC), Institutional Review Boards (IRB), and Institutional Animal Care and Use Committees (IACUC).

For purposes of this document, we refer to ethical review as the formal process described above. However, we also hope to promote it being a broader and more holistic process, one that extends beyond evaluation and approval to proceed with proposed research. We believe that consideration and prioritization of ethics (and both human/animal welfare) must permeate the full scope of a project, from the time it is first conceived through completion and sharing of results.

This broader conception of "ethical review" means that these resources should offer supplementary value for those whose projects already undergo institutional ethical review. In addition, there are several contexts that have no ethical review mandate but would undoubtedly benefit from consideration of ethics to help ensure that the impact is as positive as the intent. This Guidance Document and the **Ethical Review Toolkits** are therefore meant to help both when ethical review is mandated, and when it is not. The **Additional Resources** also contain two example forms for independent ethical review, as well as a case study of an organization that conducted such a review.

Why conduct an ethical review?

However positive the *intent* of a project, the *impact* on different stakeholders may be positive, negative, or a mix of both. Conducting an ethical review aids evaluation of the ethical appropriateness of projects and helps identify potential harms or risks so that, where possible, steps can be taken to avoid or reduce them.

Peer-reviewed journals are increasingly making prospective ethical review a mandatory criterion for accepting a manuscript for publication. If journal publication is a consideration, the project may be required to go through prospective ethical review by an institutional ethical review body.

Ethical review should be considered an empowering process, for it is protective, positive, and proactive (3Ps):

1. ***Protective:*** It provides a systematic way to identify, consider, and address ethical matters. It enables us to avoid or reduce harms and prompts consideration of whether harms are justifiable in light of the intended benefits of the project.
2. ***Positive:*** It prompts us to look for opportunities to do things better, to promote welfare or well-being in ways we had not originally considered, and not merely focus on the

reduction or avoidance of harm (e.g., refinement; humane handling; the inclusion of owners, communities, or other stakeholders in decision-making processes).

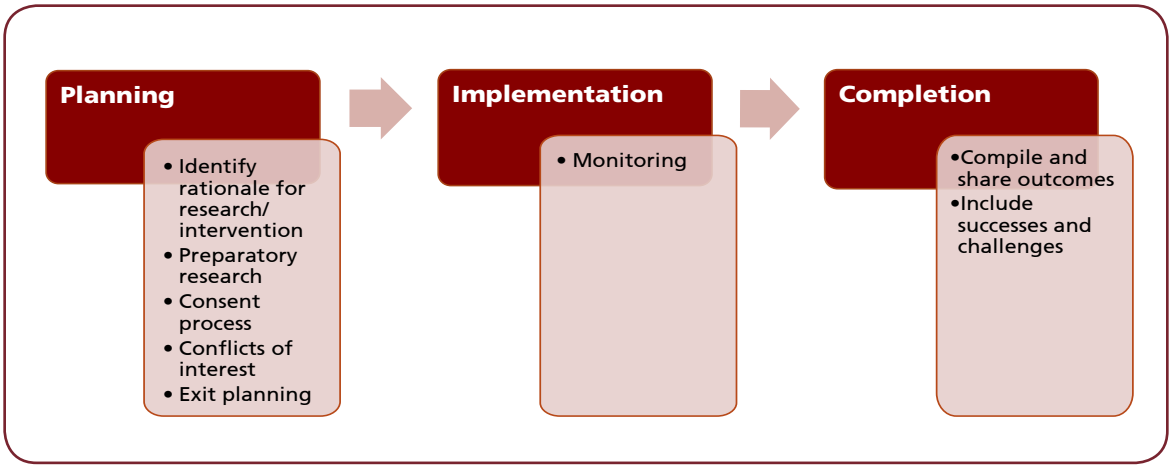
3. ***Proactive:*** It allows us to mitigate risks and address ethical issues. It promotes a positive cycle of adaptive management; we continue to learn and develop our decision-making and ethical competencies.

In addition to protecting the targets of an intervention or subjects of research, a robust ethical review can also help those implementing the project. It may reduce stress by anticipating, mitigating, and/or avoiding ethical quandaries or conflicts that projects can present, and it can increase confidence in the face of difficulties.

ETHICAL CONSIDERATIONS

See also the Data Collection Toolkit

When planning a project, it is important to address ethical considerations throughout the duration of—and even after—the project. The sections below include information, questions, and guidance to consider when planning, implementing, and completing a project.



Ethical considerations when planning a project

Ethical review boards evaluate the extent to which the ethical components of research are considered, but even in the absence of formal ethical review, good planning is important to justify your work. Below are five topics involved in good planning: 1) defining the rationale for the work you are planning to do, 2) conducting preparatory research to help inform if the project is feasible to undertake, 3) identifying how you will obtain informed consent from participants, 4) identifying and addressing any conflicts of interest, and 5) planning your exit. The material is not intended to be a comprehensive "how to" guide for planning a project, but rather to share topics to consider in relation to the ethical justification for the project.

Rationale for the project

You should have a well-defined rationale for undertaking a project before proceeding with even preparatory steps. Ultimately, you must be able to answer the question, "Is this necessary and, if so, according to whom?"

A good place to start is thoroughly understanding the "problem" or question that you are hoping to address. Who has defined the problem or question? Different parties may view situations very differently. An example is a community with a large number of dogs. The organization preparing to conduct a project may view the community as suffering from "overpopulation." However, some stakeholders might not view the *number* of dogs as a problem, but rather identify another aspect of the dog population (e.g., dog bites, barking, roaming animals, defecation) as the issue needing attention. In this case, population control alone may not immediately address the community's needs, and thus the goals or methods of the project may need to be adjusted in order to justify conducting it.

Here are some questions to consider as you take a macro-view of your project:

- What question is your work trying to answer, or problem is it trying to address?
- If you seek to address a problem, who has defined the problem, and are there alternative ways to solve it?
- Who has been included/excluded from developing the rationale for the project?
- Who is expected to benefit from the project? Will you benefit? Who may be harmed?
- What are the expected and potential negative impacts of your work? Which of these impacts are justifiable, and according to whom?
- What are the indicators of success or failure?
- Are there alternative ways to solve the problem?
- What happens if the project does not occur?

Advance research provides important information about...

- The evidence base upon which the project is designed.
- The choice and detailed description of appropriate and objective goals that are achievable and measurable.
- Whether methods to address the identified problem are valid and reliable, and represent the best choice considering all methods available and the possibility for innovation.
- The risks associated with the project, and how to optimize efficacy and safety.
- The nature, magnitude, and timing of adverse events in previous projects, and the steps that can reduce risks to stakeholders.

As you go through this process, it is imperative to consider perspectives of all stakeholders in addition to perspectives of those implementing the project.[1] (Further details on stakeholders are below.) Involving stakeholders from the very beginning provides a rich diversity of perspectives in developing a rationale for the project, or in coming to realize that it is not ethically justified.

Preparatory work

Conducting a project requires preparatory work and research. This can take place in many forms: desk-based research (reviewing published and unpublished literature, potentially including translational information from work conducted in other species), consultation with stakeholders, or site visits to better understand local conditions.

Together with other actions described in this section, preparatory work will inform whether the project can be feasibly and safely undertaken. Preparatory work is particularly important for anything novel, since you will not be able to rely on findings from previous work to make decisions about the project for which you are preparing.

Preparatory work may also include collecting baseline data to allow for impact monitoring and evaluation. It may help to identify different stakeholders and gain insight into how each may be impacted by the project. It can provide important information regarding, e.g., the nature and dynamic of the relationships between humans and animals; which animals are owned and allowed to roam, and which animals are cared for by the community; how stakeholders feel about cats or dogs; and local veterinary capacity; among other details.

Through this data gathering phase, you should gain information that can help guide project design and research protocol. Two important areas for advance work are understanding external constraints and understanding the stakeholders who are involved:

1 One way to gather input from stakeholders is to use a participatory process. For an example of how this process is used in animal welfare, see The Brooke's "Sharing the Load" manual: https://www.thebrooke.org/for-professionals/sharing-load-manual.

1. Identifying external (legal, regulatory, policy, physical, resourcing) constraints

External constraints are inevitable with any project, though the details will vary depending upon the nature, circumstances, and location of the project. Constraints can protect or compromise animal welfare. Examples of external constraints include lack of access to controlled or desired drugs for anesthesia, analgesia, or euthanasia, or inadequate local skilled veterinary care for conducting research on a new non-surgical technology.

Potential external constraints should be identified and addressed prior to starting any project. Occasionally, you might find that a constraint cannot be resolved. If this is the case, either the project should not proceed, or the rationale for proceeding should be justified and alternatives explored.

2. Identifying stakeholders and associated risks and benefits

Planning a project should include identifying stakeholders early on. "Stakeholders" include animals and humans, individuals, groups, communities, populations, or organizations that are affected by the project in any way.

"Risks" (defined here as potential harms) and benefits associated with a project should be identified for each stakeholder. Stakeholders are diverse. Some individuals will be more vulnerable, just as some individuals will have a greater potential to benefit (e.g., animals of different ages, sexes, ownership status, and welfare states; children vs. adults; advantaged vs. underserved communities).

Risks. There is no definition of "acceptable" risk for proceeding with a project, nor is there an algorithm that can be applied to identify all potential harms to all stakeholders in advance so that risk can be identified and mitigated. However, there *are* some specific issues that should be considered and tangible steps that can be taken:

- Identify all stakeholders, understand their perspectives, and give due consideration to the ways in which they can be positively and/or negatively affected by the project.
- Evaluate the welfare of animals for *all* stages of the project (before, during, and after), including assessment of direct, indirect, and contingent harms.
- Discuss risks and benefits to animals with relevant (human) stakeholders in a participatory process. A fundamental tenet of participatory research is that power is handed from the researcher (or group leading a project) to the participants, who are often community members or community-based organizations (Participate, 2018).
- With stakeholder engagement, identify whether potential harms are mild, moderate, or severe.[2]
- Consider a wide range of possible harms. Harms may include physical

2 According to the European Commission (2009) Expert Working Group on Severity Classification Criteria, degrees of harms to animals and humans are defined as follows: Mild: short-term mild pain, suffering or distress (animal); annoyance or irritation (human); moderate: short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress (animal); harms to personal standing or reputation (human); severe: severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress (animal); physical or psychological harms; impacts on livelihoods (animal).

or psychological suffering (animals and humans), or they can include risks to livelihoods, personal standing, reputation, irritation or embarrassment (humans); they can occur during or after the project.

- Recognize that the interests of stakeholders may compete, and reducing harms to one group of stakeholders may increase the risks for another.
- Work to identify if risks can be avoided or reduced, and the inherent difficulties or uncertainties in understanding the risks to stakeholders in the field.

Benefits. The more enjoyable topic to consider is benefits. In many field interventions, the benefits to one or more stakeholder group are clear. For example, mass dog vaccination campaigns to control dog-mediated rabies benefit both human and animal health and welfare (and tend to carry relatively little risk). However, where projects are aimed at advancing scientific knowledge in animal health or welfare, the benefits may be more long-term, and the justification for individual projects may be harder to determine.

Whatever the nature of the research question, projects must be designed, conducted, monitored, and analyzed in ways that enable the question to be answered with confidence.

Stakeholders

Below is more detail regarding three stakeholders: animals, **owners/guardians**, and **communities**. Each has a toolkit with a deeper dive into stakeholder-specific ethical considerations; the **Ethical Review toolkit** additionally provides details on identifying and evaluating the risks and benefits associated with a project.

Animals

ANIMALS TOOLKIT

For a project to be ethically justified, it is essential to protect the welfare of animals that are targets or subjects of the project, as well as those who might be affected indirectly. This may seem straightforward, but in reality it is quite complex. Key considerations are introduced in this guidance document; further details and resources are available in the Animals Toolkit.

- ***What "welfare" means:*** There is no universally accepted definition of "animal welfare." Here we use the term to refer to the animal's physical, behavioral, and psychological well-being. A variety of animal welfare frameworks are available to help assess animal welfare in a systematic way.
- ***Target and non-target animals:*** The most obvious stakeholders are the direct targets of the project. However, other animals in the environment may be impacted because they are associated with targeted dogs or cats (e.g., wildlife; livestock; or other dogs or cats

in the same household, street, or community). Potential harms to other animals should be identified in the risk assessment, and appropriate steps taken to mitigate those harms.

It is also important to consider the welfare and risk/benefit of individuals and populations. Individual animals in a project may not personally benefit from the research; the beneficiaries may be future generations of cats or dogs. Additionally, impacts on other animal species are relevant and should be considered.

- ***Weighing harms, risks, and benefits:*** The welfare of animals should be evaluated in relation to all aspects of the project and should include assessment of direct, indirect, and contingent risks, harms, and benefits. During the course of a project intended to advance welfare, animals may experience harm (e.g., fear, pain, or distress). For example, capture, handling, restraint, caging or kenneling, blood collection, or surgery all negatively impact animal welfare. In some cases, harms may be transient, and in others they will have lasting effects.

  There are inherent risks to animals (the potential to cause them harm) in any project, and we have an ethical obligation to identify those risks ahead of time, evaluate their severity and duration, and take steps to avoid or reduce them wherever possible. Where we cannot reduce all risks or harms, they must be weighed against anticipated benefits to decide if the project is still justified.

  It is important to note that field conditions carry different risks than more controlled environments. Risks anticipated to be mild or moderate can quickly turn severe. Moreover, peoples' abilities to quickly intervene can be limited due to many factors, such as lack of adequate veterinary care, poor animal handling, inadequate post-treatment monitoring, lack of suitable drug agents to perform humane euthanasia, or an owner's refusal to consent to euthanasia for a suffering animal.

  This is not to say that projects are filled only with risks and harms, however. While it is essential to seriously consider them before deciding to begin a project, it is also important to weigh the potential short- and long-term benefits to animals, including

Assessment App

An audit-based approach to assessing animal welfare in the field has recently been developed in App form for use by dog handlers and veterinarians working in canine catch/neuter/vaccinate/return (CNVR) programs. Behavioral data (e.g., indications of pain or fear) are recorded for each step of the intervention. With staff trained to recognize behavioral indicators of dog welfare, the App aims to identify steps where welfare is negatively impacted so that operators can refine their practices and improve animal welfare.

The App can be downloaded through the: Jeanne Marchig International Centre for Animal Welfare Education.

protection from disease and/or death, health and welfare benefits associated with not birthing multiple litters of puppies or kittens, protection from culling, or improved treatment by the community, owners, and guardians.

Fundamentally, the goal is to ensure that harms to animals (and other participants and stakeholders) are avoided, or at least reduced to a minimum, and that the chances of achieving the benefits are maximized. The harms and benefits are then weighed against each other (the harm-benefit analysis) to decide whether the project is justified and it is acceptable to proceed.

- ***Measurement and monitoring:*** In order to identify risks to animal welfare, to anticipate their severity and duration, and to apply the necessary safeguards to avoid or mitigate those risks, we suggest adapting a structured "road mapping" approach. Including persons with local knowledge in discussions will help identify specific relevant challenges.

  Methods of measuring welfare indicators should be feasible to use under field conditions, valid, and reliable. The project protocol should clearly identify the process for assessment, who is responsible for assessment, and steps required for remedial action to address welfare issues that are detected during or caused by the project.

Owners, guardians and caretakers

Owner, Guardians and Caretakers Toolkit

Owners, caretakers, and guardians should be included in decision-making processes regarding inclusion of their animal in a project, and they should be informed of the benefits and the risks using appropriate language for the person or persons' circumstances (e.g., education level, familiarity with the project). This is also true for obtaining consent or permission for participation.

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Working with humans in field projects is made more challenging by the need to engage a broad spectrum of owners, caretakers, and guardians. At one end of the spectrum, "owners" are legally recognized. Dogs and cats may also have one or more people who provide some care and identify as "owners" or "guardians," be "community" animals, or, much less likely, be truly unowned.

The variable and complex relationships that dogs and cats have with humans can contribute to projects causing harms to the people involved. Therefore, the characterization of risk and benefits to people must take into account the nature of the relationship with the animal.

The highly variable and complex relationships between animals and humans *also* can cause both logistically and ethically challenging scenarios and questions. For example:

- How do you work with individuals who want their animal to take part in a research or non-research-based project for seemingly "wrong" reasons?
- What if an owner or guardian is not acting in the best interest of an animal—e.g., is against euthanizing a dog or cat who is suffering?
- Do you need consent from all individuals who exert "loose" ownership of an animal to enroll that animal in a project?

For a deeper dive into this topic please see the **Owners, Guardians and Caretakers Toolkit**.

Communities

📂 Communities Toolkit

Communities are broader than owners, caretakers, or guardians; they include people who have no direct interaction with dogs or cats, government officials, local non-profit organizations, and more. Communities are important stakeholders, particularly for projects focusing on population management or rabies vaccination campaigns, and they can be

critical to allowing a project to proceed or sustaining its benefits upon exit. Without their support the project is unlikely to achieve its intended goals. Moreover, a poorly implemented project can quickly jeopardize the success of future projects from which the community and its animals might benefit.

Communities are not homogenous. In fact, communities may be quite polarized about animals, creating volatility in discussions about a project. Different religions or cultural norms may shape different perspectives about dogs and cats. Animals may elicit fear or revulsion among some, but not all, community members. Some community members might be eager for the project, while others might be inherently wary because of previous experiences (e.g., past projects were unsuccessful or harmful, communities were not consulted in the decision-making process).

These possibilities are all the more reason to get to know how the community works, build trust, and become familiar with pertinent issues *before* concluding that a particular community is appropriate for your project. Use of a participatory process with robust community engagement creates important opportunities to identify both ethical issues and processes for resolving ethical issues when they arise.

In short, community engagement:

- Creates opportunities to improve consent processes.
- Helps to identify ethical issues in advance.
- Creates avenues and processes for avoiding, mitigating or resolving ethical issues when they arise.
- Creates opportunities to incorporate local knowledge, experience, and ideas for achieving the goals of the project.
- Empowers communities in decision-making surrounding the design and conduct of the project.
- Ensures the perspectives of community stakeholders are included in ethical review processes.
- Creates relationships and trust between and among communities, researchers, and organizations.
- Where relevant, can increase potential for sustained changes/benefits following the project.

The **Communities Toolkit** offers extensive and detailed information and guidance on working with Communities as part of a project, including step-by-step instructions on how to effectively partner with a community to begin an animal welfare project. A companion **Stakeholder Identification & Analysis Toolkit** offers tangible strategies to help identify stakeholders who need to be involved and consulted at each stage of a project. The Communities toolkit offers holistic information and a holistic approach that incorporate some principles from other toolkits.

Consent and permission

Informed Consent/Permission Toolkit

Consent and permission are related to stakeholder risk, including the sharing of personal information. The ethical principle that every person has the right to self-determination is reflected in "informed consent." Prior, voluntary informed consent to participate in a project is established by research codes promoting the well-being of humans when information or data is gathered, and it is an important consideration if you are collecting any personal information about owners or guardians as part of the project.

When working with owned or community dogs or cats, voluntary informed consent is essential but likely limited to instances where owner interviews solicit personal information. When approval for an animal to participate in a project comes from a selected agent or proxy (the owner or guardian), what is provided is arguably permission rather than consent—a distinction that might not affect actions from a practical standpoint but becomes ethically relevant when considering how we best respect the autonomy of animals as research subjects or project participants. To begin to answer this question, we can look at ethical guidelines for projects involving humans who cannot offer informed consent (e.g., children or adults with compromised intellectual capacities), as these populations receive special consideration by researchers and research ethics committees (CIOMS, 2016).

Additional challenges include the fact that animals don't always have a single "owner." Moreover, definitions of "ownership" and "guardianship" vary, vulnerable individuals (especially children) might be responsible for animal care, and disparities between those implementing a project and the target animal-owning populations can call into question whether owners are sufficiently empowered to say "no" to participation.

For projects or other interventions that are known to carry little-to-no risk and where an owner/guardian takes the initiative to bring the animal for participation, implied permission might be adequate. This assumes that a person agrees to something based on his or her actions. An example would be a vaccination campaign, where an individual brings his dog to receive a rabies vaccine.

Other situations warrant a more extensive dialog (exchange of information to enable a person to make a free and informed choice) and plans for how to obtain informed consent or permission. These need to be tailored to the level of anticipated risk to owners/guardians and their animals, the individuals from whom consent is being sought, and the local conditions.

Challenges to seeking, obtaining, and documenting informed consent or permission in the field should be identified during the planning stage, and strategies for managing these challenges should be stated in the project protocol.

Conflicts of interest

CONFLICTS OF INTEREST TOOLKIT

The term "conflict of interest" broadly describes a situation where a person carrying out an action is—or is perceived to be—unable to make an unbiased decision. Competing interests can threaten the integrity of a project and be detrimental to the well-being of its stakeholders and intended beneficiaries.

Exit

Planning for a project requires planning for exiting or stopping it. The optimal reason for stopping is that the intended impacts or data collection are achieved according to a predetermined timeline and in a way that causes no harm to stakeholders. However, this may not be the reality. Common reasons for exiting earlier than anticipated include compromised welfare of a stakeholder group, increased risks of harms or reduced intended benefits to stakeholders, lack of funding, or evidence that the project is not achieving its intended outcomes.

Halting a project requires determining what happens after you leave, as well as ongoing responsibilities to different stakeholder groups. Stakeholders should also be made aware of the potential exit points and the conditions or considerations under which you may exit the project earlier than anticipated.

Criteria and plans for exiting should be made, as far as possible, *before* beginning the project, and the project monitored against those criteria.

Ethical considerations while implementing a project

All projects require conscientious oversight through ongoing monitoring. Monitoring helps to recognize and understand the project impacts, ascertain if the project is effectively addressing the problem that necessitated the engagement, and, for research specifically, determine if results warrant or justify continuation.

Monitoring has ethical dimensions, as it can help ensure that predicted risks to stakeholders are effectively managed, that unexpected harms are swiftly addressed, and that protocols and standard operating procedures are followed correctly. Having space to "capture" ethical issues that were not anticipated in your monitoring and evaluation plans and reports can be valuable; they can be included in lessons learned at the end of project evaluation or impact assessment.

Ethical considerations upon completing a project

The decision of whether or not to compile and share important findings and learnings from a project or non-research-based project is arguably an ethical one. Efforts should be made to:

- Ensure that findings and learnings are available to all persons (open-source, either through peer-reviewed publication or other means), especially the stakeholders. It is essential that the findings and learnings are available in the language(s) and format(s) appropriate to all stakeholders.
- Publish not only positive data, but also *negative* data to prevent wasteful or unnecessary repetition.
- Share what worked and what did not work; this will help others make better decisions and positive changes to future projects, and prevent repeating interventions where harms were found to outweigh the benefits (thus making them ethically unjustifiable).

SUMMARY

This guidance document was developed with the intention of providing an overview of ethical considerations related to field-based projects, including but not limited to research, that target dogs or cats. It covers actions that can be taken to ensure that projects take into consideration the needs of, and responsibilities toward, the many stakeholders who will be impacted.

For more information on specific topics, as well as case studies that bring these topics to life, please visit the appropriate toolkit. We also encourage you to view a comprehensive **list of ethical considerations for field projects** in the Additional Resources section of this document

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FURTHER READING

List of Ethical Questions & Considerations

KEY THEMES TOOLKITS

SECTION CONTENTS


BACK

ETHICAL REVIEW TOOLKIT

INTRODUCTION

Ethical review is a systematic process intended to help identify the potential harms, risks, and benefits in projects on or with animals or humans. It helps identify ethical issues raised by such work and evaluate whether it is ethically appropriate for the project to go ahead. The goal is to ensure that harms for all participants and stakeholders are avoided, or at least reduced to a minimum, and that the chance of achieving the benefits is maximized. The harms and benefits are then weighed against each other (the harm-benefit analysis) to decide whether the project is justified and it is acceptable to proceed.

Ethical review is most commonly applied in scientific research using animals, as well as in medical or veterinary clinical trials and studies requiring data collection from humans or animals. However, both principles and practice can be readily adapted to other kinds of projects, such as a veterinary contraceptive or rabies vaccination program in the field.

Ethical review requires a carefully considered, conscientious approach, and should never be considered as just a box ticking exercise. It should be seen as a dynamic process, not as a single event before a project is started. Harms and benefits can change as a project progresses, so the assessment and weighing of both aspects should be considered at regular intervals, particularly if unexpected harms become apparent or there is doubt about the actual benefits.

Consideration and prioritization of ethical issues (including both human and animal welfare) must therefore permeate the full scope of the project from the time it is first conceived (prospective review) through completion and sharing of the results (retrospective review).

Formal ethical review should be performed by an ethical review body. The composition of such bodies varies depending on the legal, national, local, or professional requirements governing the individuals or organization and the type of work to be reviewed. Often a basic minimum membership is specified, but inclusion of a wider range of expertise and perspectives relevant to the nature of the work under review is encouraged as good practice.

Further information on ethical review bodies is given throughout the following sections, together with advice on what to do if there is not a formal ethical review body already set up and readily available with the relevant expertise to review a proposed project. The Additional Resources at the end of this publication also contain example forms and structures for independent ethical review, as well as a case study of an organization that conducted an independent ethical review to supplement an institutional ethical review process.

THE IMPORTANCE OF ETHICAL REVIEW

Ethical review is widely accepted as being integral to the conduct of humane, responsible research and associated activities involving humans and/or animals. It is increasingly required by regulatory and professional bodies that govern, fund or publish such research, examples of which are summarized below.

- ***Legal requirements:*** In many countries ethical review is a mandatory requirement for scientific research on animals and for studies on humans, including clinical studies, interviews, and collection of personal data. In such cases it is usually carried out by a formally constituted ethical review body or ethics committee. More information on formal ethical review bodies and the requirements in different countries is provided in the next section.

  Veterinary clinical studies and surveys are subject to veterinary legislation and professional codes of conduct, which may also include a requirement for ethical review.

  Whenever data is gathered from humans and/or animals, they are considered research subjects or participants, and the data gathering may require ethical review even though the project itself may not do so.
- ***"Local" requirements:*** Even where there is little or no specific national legislation, there may be a local requirement for ethical review by a recognized ethical review body. It is particularly important to check whether this is the case whenever a project is undertaken in a different country to that where the organization responsible for its design and conduct is based.
- ***Professional codes of practice:*** Many professional bodies have associated codes of practice or conduct that require research-based projects to have undergone formal ethical review by a recognized competent ethical review body.
- ***Declaration of Helsinki:*** Developed by the World Medical Association, the Declaration of Helsinki is a set of principles regarding medical research on humans. The Declaration's primary purpose is to promote and protect the health, well-being, and rights of patients. It forms the cornerstone of human research ethics and is often referred to by other research codes of practice (World Medical Association 2013).
- ***Funding bodies and donors:*** Funding bodies and donors are increasingly demanding formal prospective ethical review as part of the high standards they expect from the organizations they fund.
- ***Peer-reviewed journals:*** Professional journals are increasingly making prospective ethical review a mandatory requirement for acceptance of a manuscript for publication. Authors who have not obtained suitable prior ethical approval risk having articles rejected.

These kinds of formal requirements should always be established at an early stage in the planning process for any project. However, ethical review is clearly so important that, even if there are no formal requirements, the submission of all proposed projects to such a process should be regarded as an integral part of an organization's professional standards and culture of care.[1] It benefits the work the organization undertakes, promoting humane respectful approaches towards all of the stakeholders involved. It is protective, positive and proactive (the 3Ps).

Ethical review and the 3Ps

1 PROTECTIVE

Ethical review provides a systematic way to identify, consider, and address ethical matters. It enables us to avoid or reduce harms, and where they cannot be avoided or ameliorated, it prompts consideration of whether harms are justifiable in light of the intended benefits of our work.

2 POSITIVE

It prompts us to look for opportunities to do things better, to promote welfare or well-being in ways we had not originally considered, and not to focus just on the reduction or avoidance of harm (e.g., through refinement of procedures; more humane handling of animals; the inclusion of owners, communities, or other stakeholders in decision-making processes).

3 PROACTIVE

It allows us to take action to preempt and prevent risks and ethical issues.It promotes a positive cycle of change – we continue to learn and develop in our decision-making and ethical competences, getting better over time.

WHAT IS AN ETHICAL REVIEW BODY?

The term "ethical review body" is used to describe a panel of individuals with relevant expertise and diverse perspectives that are brought together to review and advise on the ethical acceptability of interventions involving humans or animals.

The terms used to describe ethical review bodies, their membership requirements, precise role, and list of tasks differ depending on national legislation and regulations, their level of authority, and the nature of the research they review.

1 The term "culture of care" is better understood in human health and care-giving contexts, where the concept of caring within a culture refers to a pattern of shared beliefs, social norms, and routines. Culture of care is reproduced through learning from others via social interaction, which shape how care is practiced at the local level (Rytterström et al., 2013). Culture of care is co-created through the interactions, communications, influences, and collaborations among members of that community (West et al., 2014). Similar principles have been defined for institutions carrying out scientific research on animals (see EU, 2014; Jennings and Smith, 2015; RSPCA/LASA, 2015).

Examples include:

- **Animal Welfare and Ethical Review Bodies (AWERB), UK.** Under the UK Animals (Scientific Procedures) Act 1986, all establishments breeding or using animals in research must set up an AWERB. The AWERB is "a local framework acting to ensure that all use of animals in the establishment is carefully considered and justified; that proper account is taken of all possibilities for reduction, refinement and replacement (the 3Rs); and that high standards of accommodation and care is achieved." It carries out an ethical review of research projects at an institutional level with the formal government review subsequently carried out by the Home Office.
- **Regional Ethics Committees, Sweden; Animal Ethics Committees, Australia.** These committees all have the same basic role as the UK AWERB and Home Office regulatory Authority, i.e., undertaking ethical review of projects using animals in scientific procedures and ensuring good husbandry practices and that the 3Rs of humane research are implemented.
- **Institutional Animal Care and Use Committees (IACUC), USA.** IACUCs meet the national regulatory requirements for a committee to oversee institutional animal use in research, breeding, or supply in order to ensure such institutions comply with the relevant policies, guidelines, and principles governing animal research.
- **Institutional Review Boards (IRB) or Independent Ethics Committees (IEC), USA.** IRBs/IECs are tasked with protecting the safety and rights of human participants in clinical trials. They meet the national and international regulatory requirements to provide a framework and panel to ensure that regulations that guide the review, approval, and conduct of human research are met. Populations or individuals that are considered to have reduced capacity for decision-making (e.g., children, prisoners, those that are cognitively impaired or economically disadvantaged), and that may be vulnerable to exploitation, are afforded special consideration before inclusion into research studies. This includes the

requirement for their interests to be represented on ethical review bodies by individuals with expert knowledge about their potential vulnerability.

- **Ethics Committees (EC) or Research Ethics Committees (REC), many different countries.** Based at universities or equivalent research institutions, ECs/RECs serve at department, subject, or discipline level (e.g., Psychology, Social Sciences, Biological Sciences, Engineering), providing review services to their researchers, helping to meet the institution's obligations to research ethics outlined by funding bodies and relevant codes of practice.

HARM-BENEFIT ANALYSIS

Harm-benefit analysis provides a framework for decision-making and is the foundation upon which an ethical review is based. It provides a systematic way of thinking through and assessing the likely harms and potential benefits of a particular activity for all participants and stakeholders. Ways of avoiding or reducing the harms can then be identified, and the likelihood of achieving the benefits maximized through good experimental design and conduct with careful monitoring and analysis of results. These factors are then weighed against each other (the harm-benefit analysis) to decide whether it is justifiable and acceptable for the research project or field activity to proceed.

The harm-benefit analysis is not a quantitative procedure. There is no prescribed or universally accepted algorithm for how to perform it, any more than there is for us when we weigh the pros and cons of different actions in our daily lives. One problem is that there is debate about what exactly the "weighing" of harms and benefits should mean in practice. A particular difficulty, especially in research using animals, is that the factors to be "weighed" are usually not directly comparable. The suffering caused to individual animals must be weighed against benefits to humans or other animals. In such circumstances it is debatable whether it is ever possible to say that the predicted benefits "exceed" the harm to the animals used in the research.

Thus, a harm-benefit analysis does not automatically provide an "answer" to any ethical dilemma; this will be a matter of "collective moral judgement" that depends on the particular circumstances in each individual case. It requires careful and critical evaluation of all of the relevant factors by people who have the appropriate expertise, together with those who can provide a wide range of perspectives on the issues under discussion. This helps to ensure that judgements are based on well informed arguments that are sensitive to the different ethical nuances and perspectives bought forward.

There are several good reports on the harm-benefit analysis as applied in scientific research using animals (see APC, 2003; Brønstad et al., 2016; ASC, 2017). These provide detailed information on principles and practice, which can usefully be applied to other types of research or field project. Some of the factors to consider when assessing the harms and benefits of a project are introduced below.

Assessing harms

Harms to animals. The likely sources of harms to animals—both physical and psychological—in laboratory experiments are well documented, and some of these will also apply to field projects, data collection, and other interventions. For example:

- Handling and restraint of animals is common to most projects and can be very stressful (for both animal and handler) if done poorly without consideration of the nature of the individual animal.
- Identification procedures such as ear notches or tags can cause momentary pain and distress, and may cause longer term welfare issues, for example, if tags are not properly placed or fitted.
- Procedures (e.g., injections, blood sampling, or surgery) used in projects all cause some degree of discomfort, distress, or pain, which, in the case of surgery, may be severe. Euthanasia has the potential to cause a great deal of suffering if poorly conducted or done using an inappropriate technique.

It is considered good practice to use "welfare assessment score sheets" to assess levels of pain and distress using factors such as the appearance and behavior of the animals and observation of their body functions where practical. Appendix 1 of the European Commission report on assessing severity (EC, 2012) includes a glossary of clinical observations and a structured approach to observing these. For further practical information on score sheets, see section 2.4 of Hawkins et al. (2011). In some countries (e.g., the UK and throughout the EU) harms are classified as mild, moderate, or severe and the cumulative effect of a series of procedures is taken into account when assessing overall harm (see EC [2012] for further explanation and examples).

Harms for human participants/stakeholders. Animal care staff and veterinarians working in laboratories or animal shelters can suffer serious distress from having to euthanize animals, and the same will apply when working in the field. It can also be difficult when the practical difficulties of working in some field situations cause individuals to feel that their personal ethical standards may be compromised, albeit for a good reason.

Individual participants within a community can also suffer psychological harms associated with being asked to reveal information about themselves or their animals (e.g., embarrassment, guilt), or when they are asked to do something that is contrary to their culture or their individual or community beliefs.

More detail on this topic is provided in the:

- Data Collection and Use Toolkit
- Owners, Guardians and Caretakers Toolkit
- Communities Toolkit

Assessing benefits

Being clear about the nature of the intended benefit of a project—what it is, who it is for, and how likely it is to be achieved—are all important factors in assessing benefit. In many kinds of field projects, the benefits to one or more individual animals, the broader animal community, or the various human stakeholder groups are obvious. For example, mass dog vaccination campaigns to control dog-mediated rabies benefit both human and animal health and welfare, as do projects aimed at humane management of dog or cat populations.

However, where projects are aimed at advancing scientific knowledge in animal health or welfare, the benefits may be more long term so harder to assess, and the justification for individual projects may therefore be harder to determine.

A DYNAMIC PROCESS, NOT A SINGLE EVENT

As stated earlier, ethical review is a dynamic process, not a one-off event performed at a single point in time. There should be an initial prospective review at the planning stage before the project is initiated. This should examine what you plan to do and why you plan to do it. It should identify all the likely harms and/or risks for all participants (animals and humans), and set out ways to avoid or reduce these. It should clearly explore the benefits and the likelihood of achieving these so that a harm-benefit analysis can be made.

Since harms and benefits can change over the course of a project, it is good practice to periodically review how well the project is progressing, and whether the harms and benefits are as expected. The timing for this intermediate review depends on the nature of the project and how long it is likely to continue; it can be scheduled according to predetermined milestones at the start of the project, or it may be ad-hoc in response to a required change

to the project because of unanticipated ethical issues (e.g., adverse events impacting animals or humans).

At the completion of a project, a retrospective review should be carried out. This is important as part of an impact assessment to see whether the goals have been met, and to try to quantify the difference made. It also allows for a check on whether the harm-benefit predictions at the start were correct, and it can thus inform future decision-making.

Note that even though you may go through an ethical review process, you may not be able to predict all risks. No matter how well you have prepared, you may find yourself confronted by ethical issues once in the field. It is therefore a good idea to have a system in place to enable you to seek further advice when unexpected decisions need to be made quickly.

GAPS IN EXISTING ETHICAL REVIEW FOR FIELD PROJECTS

Existing ethical review bodies fulfill a specific purpose that relates to the protection of research subjects or participants within the relevant scientific, medical, or veterinary field. Their composition and duties are tailored to such purposes, and they may not provide sufficiently robust or tailored ethical decision-making for field projects, which differ in many ways from traditional laboratory-based research. Although existing guidelines set out some very useful principles and describe useful practices, both principles and practice may require additional consideration or adaptation in order to be a good fit for field projects. The following factors therefore need to be taken into account:

- Field projects and interventions require multi-sectorial collaboration in the field, including, for example, local veterinary practices, government and university departments with an interest in animal and human health, local animal welfare partners, and local community groups (see the Communities and Stakeholder Engagement Toolkits for more information).
- They are multidisciplinary in nature with a whole range of scientific and other approaches employed. Projects can involve studies in animal welfare, animal behavior, veterinary science, and social science. Quantitative, qualitative, and participatory approaches involving collection and analysis of biological samples, observation of animals, questionnaires to owners or communities, and epidemiological or statistical modeling techniques may all be used (see the Data Collection and Use Toolkit for more information).
- They have many stakeholders whose perspectives need to be represented in ethical review, including animals, their owners, veterinarians, animal welfare organizations, and others in the community who care for animals, as well as local authorities and project funders.
- They may have stakeholders spread across different countries whose interests, experiences, circumstances,

and priorities are different, but who are brought together for a common purpose: to carry out a project to benefit animals and the local community in a particular location (e.g., dog or cat population management projects funded by international animal welfare organizations).

- The animals involved are not "traditional" research models. They are not afforded the same legal protection as animals used for experimental or other scientific purposes. They are not bred for this purpose or housed and cared for by qualified staff in breeding or research establishments with legally required minimum standards. Nor are there any requirements to apply the 3Rs principles of humane science (Replacement, Reduction, Refinement). Owned animals may have legal protection from cruelty, and their caregivers have obligations to provide for their welfare needs (e.g., with food, water, shelter, and basic veterinary care). Unowned animals, or those cared for by communities, may be afforded no legal protection to safeguard their welfare.

PRACTICAL APPLICATION OF ETHICAL REVIEW

For some projects, a formal review process through a designated ethical review body may be mandated, and the need for such a review should always be checked early on in the planning process. However, whether or not this is required, most projects will benefit from an initial voluntary review by the person and/or organization initiating the project. This is particularly true if there is no established review process for the type of project you are conducting. A suggested process is as follows (see also Appendix 1):

1. Undertake a thorough internal review process; try to identify the ethical issues related to the unique set of circumstances regarding the project you or your organization is hoping to carry out. If necessary, gather more information by exploring the literature or taking inspiration from the approaches of other organizations, published guidance, case studies, or toolkits.

2. Use the List of Ethical Considerations and Toolkits to help identify and map harms, risks, and benefits and guide your decision-making processes in a systematic way. If necessary, review qualitative and quantitative data that help you understand risk.

3. Talk things through with other people in the organization. Identify external individuals or organizations that have a "stake" in the project, then gather a broad range of perspectives from people that represent the interests of all stakeholder groups likely to be involved.

4. Check whether existing formal ethical review bodies have the necessary expertise and competency to offer robust review processes suitable for your purposes, i.e., to allow for accurate consideration of the impacts on all stakeholders. They would need to reflect the ethical challenges likely to be faced, and the contexts of those challenges. An understanding of the varying relationships dogs and cats have with humans, and how this affects the way in which we consider harms, is required. The review body would need to be mindful of how

CASE STUDY

Brooke's use of an ethical review process to protect animal and human welfare

Brooke is an equine welfare NGO that works in Asia, Africa, and Latin America. The organization addresses welfare issues affecting the world's 100 million-plus working equids (horses, donkeys, and mules) and the people who care for those animals. Its work takes place predominantly in low- and low-middle-income countries with comparatively vulnerable populations. Although it does not involve dogs and cats, we believe this case study is quite applicable to discussion of ethical review.

To support its programmatic and advocacy work, Brooke undertakes two forms of research. Non-invasive animal-based research is designed to improve understanding of causal factors associated with a welfare problem or clinical issues facing service providers, or to evaluate whether a novel intervention in a field setting achieves the desired welfare benefits. Human-based research, conducted via interviews or focus groups, aims to understand attitudes and practices of key stakeholders, define the contributions that equids make to human livelihoods, and investigate the relationships between animal and human welfare. It would be easy to undertake such efforts without viewing them as "research," but they are very much so insofar as they collect field data to both improve the services of Brooke and the well-being of the organization's human and equine stakeholders.

The organization discusses its specific hurdles to obtain informed consent; the principles established by the Declaration of Helsinki shine light on a host of practical challenges that Brooke faces when conducting research. A complete list is available in Upjohn and Wells (2016), but examples include:

- As animals are property and cannot themselves give informed consent, owners are required to make good judgments about their animal's involvement. How can this be done in a situation where recognition of animal welfare may be less widespread, and owners' appreciation of animal behavior may be limited?
- Can an animal refuse to assent to treatment by way of its behavior?
- How can voluntary human participation in a study be ensured in a context where there is an existing dependency?
- How is information about a study effectively transmitted to participants who may be poorly educated and/or illiterate, and how is participants' understanding verified?

To address these tricky ethical questions, Brooke adopts a holistic approach that also addresses the individual components of the Declaration of Helsinki. It "aims to embed a culture of care for the animals and owners with whom we work in all staff," which aligns the organization closely with a social anthropology approach to research. It has established an Animal Welfare policy with non-negotiable practices (enforced by senior management) relating to research with equids and those animals' owners and users.

These practices "ensure that the welfare of the animals and their owners are paramount. All members of staff are charged with ensuring that the risks to animals and people as a result of Brooke's activities are minimized. The policy states that country program staff is responsible for seeking informed consent and ensuring that the dignity, rights, safety, and well-being of research participants are considered and that any potential risks are mitigated."

The organization also has its own Animal Welfare and Ethical Review Body (AWERB) consisting of a chair, executive secretary, and five advocate roles encompassing expertise in animal welfare, veterinary care, study design, and human welfare, as well as a layperson. The AWERB is charged with reviewing research proposals and protocols using people and/or animals as subjects to ensure appropriate compliance with ethical principles.

It is important to note that an internal AWERB is not a legal requirement of animal welfare NGOs, which is why many NGO projects are undertaken without any ethical review of protocols—a reality that can have severe consequences on stakeholder well-being.

We applaud the organization for establishing an AWERB to protect both the animals and the humans with which—and for whom—it works, and we encourage this to become a more common practice among NGOs.

For more information, see: Upjohn, M., & Wells, K. (2016) Challenges associated with informed consent in low- and low-middle-income countries. Frontiers in Veterinary Science, 3, 92. doi: https://doi.org/10.3389/fvets.2016.00092

these animals differ from either traditional animal research subjects housed in laboratories, or from free-living wildlife, and it should consider including review panel members with the additional expertise and competencies for effective project evaluation in this area of work. Providing them with these guidance materials may help to better inform them of the ethical issues you face in the field.

5. It may be necessary to submit projects to more than one formal review body (e.g., IACUC/AWERB and IRB/EC/REC) depending upon their scope and level of authority, and therefore to go through more than one ethical review process. Where the review panels have different expertise, when combined they can better consider the effects of the project on both animals and humans. It may be that if more than one review body exists within an individual institution (e.g., IACUC/AWERB and IRB/EC/REC) the separate processes could be combined to save time.

6. If your project spans more than one country, find out whether and what kind of ethical review is required locally. Be mindful that local review services may be limited in scope, experience, and competencies.

7. Help to set up an independent ethical review body whose panel (composition, expertise, competencies, etc.), aims, and tasks better suit the review purposes required for your project. Depending on the nature of your work, this could be an ad-hoc review body, or a permanent "bespoke" review panel.

See the Additional Resources section for two example forms for independent ethical review, as well as a case study of an organization that conducted such a review.

MEMBERSHIP OF ETHICAL REVIEW BODIES

The quality of ethical judgements depends on the collective expertise, perspectives, and integrity of those making them, so the composition of ethical review bodies affects their ability to deliver robust ethical review of projects. The membership of most ethical review bodies is determined by the regulations under which they are established.

The structure and responsibilities of ethical review bodies—namely, having individuals with relevant expertise review research—are widely applicable. However, existing ethical review bodies may not be "fit for purpose" for projects involving cats and dogs in the field. ***Table 1*** suggests the type of specialists and perspectives that may be needed to provide a dedicated ethical review body for this type of work, or who could be invited to join existing committees to make their review process more applicable.

However, expertise is not the only issue. Panel members need to have the personal qualities that enable them to operate effectively, and these are shown in ***Table 2***. Good chairmanship is also essential to ensure that the focus is on outcomes, the process is efficient, and everyone has the opportunity to contribute and express opinions, as well as to set the right tone. The Chair needs to create a supportive, inclusive environment where everyone is listened to and in which open and forthright discussion is encouraged (RSPCA/LASA, 2015).

Table 1: Membership Requirements – Knowledge and Expertise

Knowledge/Skills	Profession	Representing Stakeholder/ Stakeholder Issues
• Cat/dog behavior and welfare • Conduct of observational behavioral studies • Multidisciplinary welfare assessments • Human-animal bond/ relationships • Study design, data analysis	Animal welfare & behavior scientists	Animals Owners/guardians Variation in human-animal relations Scientific quality
• Cat/dog health and welfare • Field conditions – practical limitations to practicing veterinary medicine and surgery in the field	Veterinarians	Animals Owners/guardians Veterinary practices/ veterinarians in the field
• Human participants in quantitative and qualitative research in a range of field settings • Human-animal bond • Psychology of owners/guardians • Community-related factors • Study design, data analysis	Social scientists, Psychologists, Ethnobiologists	Human well-being Owners/guardians Communities Impact of the human-animal bond Scientific quality
• Risk/hazard assessment • Conduct of field trials • Converting data derived from laboratory studies to characterize risk in the field • Compliance	Statisticians, Veterinarians with field experience	Animals Environment Understanding of risks and hazards in the field Scientific quality
• Bioethical perspectives • Asking important ethical questions • Guiding ethical debate and deliberation	Ethicists/bioethicists	Ethics Bioethics
• Wider stakeholder perspectives • Local stakeholder perspectives • Vulnerabilities relating to other stakeholders posed by intervention or innovation	Lay members	Wider stakeholders Openness and Transparency

Table 2: Membership Requirements — Personal Qualities

Personal Qualities
• Being open-minded, fair, and impartial • Being confident to express a personal view in a non-confrontational way even if the view is considered controversial • Being prepared to listen and respond to differing views and not be unnecessarily judgemental • Being prepared to think outside the box and have the confidence to question the status quo • Having realistic expectations of what can be achieved • Having the time and commitment to make an active and informed contribution and do the role justice

Encouraging wider ethical debate and discussion

Ethical judgements on what is or is not acceptable to do to animals under different legislation and in different cultures changes with time. It is therefore good practice to create a constructive environment within your organization where ethical issues beyond just the review of individual projects can be discussed and thinking on ethical issues developed. This issue has recently been advanced in a report on "The AWERB as a Forum for Discussion" (Hawkins & Hobson-West, 2017).

Recommendations focus on improving the "quality" of ethical discussion, widening engagement across an organization, and encouraging openness beyond the organization. Some ideas are:

- Allow the necessary time and space for wider ethical debate and suggest relevant (and interesting) topics.
- Invite external speakers/experts to participate in the debate/facilitate ethical discussions.
- Encourage expression of differing viewpoints.
- Create opportunities for wider engagement of staff in ethical review process meetings in your organization
- Include ethics and ethical review processes in all staff training and induction programs.
- Make the ethical review process transparent.
- Provide a dedicated information portal and/or intranet site with information in a readily accessible format for all employees.
- Produce lay summaries for staff and non-scientific participants in studies and interventions in a simple and easy to read format without technical language.

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APPENDIX 1

Illustrative approach to ethical oversight spanning the lifetime of a project

Prospective - at the planning stage for the project	
Internal ethical review processes: within organization and between stakeholders	
Goals	**Potential Steps**
To provide a comprehensive ethical review which includes: • A detailed harm-benefit analysis plus identification of any other ethical issues. • An assessment of all potential risks • Steps to avoid or reduce harms in the design and conduct of the intervention and associated monitoring, evaluation and impact assessments. • Steps to maximize chances of achieving the desired benefits • A risk-management strategy for dealing with unforeseen ethical and practical issues if these arise during the project. • A plan for intermediate and retrospective review.	> Identify internal (if any) and external review processes that are required (e.g., mandatory legal, institutional, or local; or by academic or institutional collaborators; by funders and journals; or by your own organization that may wish to voluntarily submit proposals for external review). > Identify key personnel in your organization that should be part of the decision-making process (include a broad range of perspectives; consider knowledge, skills, interests, and competencies). > Identify constraints (e.g., legal requirements, physical environment, skills, or professional capacity). > Identify conflicts of interest and how these will be dealt with. > Consult with stakeholders. > Identify and budget for costs associated with using an external review process (if relevant). > Adapt plans for the project based upon internal review processes. > Define timing for intermediate review. > Nominate a person or persons to ensure that relevant indicators and methods of measurement are included in monitoring and evaluation plans to enable intermediate ethical review to be performed. > Put a decision-making pathway in place for dealing with unforeseen practical or ethical issues should these arise during the project (e.g., who to contact for advice in a crisis). > Provide a forum for discussion and reflection on ethical issues with identified personnel in your organization.

Prospective - at the planning stage for the project	
External ethical review processes: submission to external ethical review bodies	
Goals	**Potential Steps**
To meet the requirements of mandated and/or voluntary external review processes and gain external ethical approval for the intervention to proceed; and to include recommendations from external review processes into the design and conduct of the project where these would be beneficial.	> Nominate an individual or individuals from your organization who will be: • responsible for liaising with the ethical review body. • checking what information is required and submitting the necessary application forms. • ensuring reviewers' queries and recommendations are addressed. • ensuring any required changes are incorporated into the project plans. > Identify the requirements and timeline for external ethical review processes well in advance to allow you to complete the full process before you start the project. > Find out if an intermediate or retrospective review is required. > Submit your application with sufficient information for the review body to be able to evaluate it fully (including details of what you propose to do and why; how you are going to carry out the work; the harms you have identified, and the steps you have taken to avoid or reduce those harms; and how you intend to maximize the chances of achieving the benefits).[1] > If required, revise plans and resubmit your application.

1 Formal ethical review bodies will have standard forms and guidance notes to help you provide the necessary information. If in doubt, ask them for advice.

APPENDIX 1 continued...

Intermediate - as the project progresses[1]	
Internal ethical review processes: Within organization and between stakeholders	
Goals	**Potential Steps**
Goal is to achieve: • ongoing review of ethical considerations while the project is underway; and • adaptive, risk-based management of the project as embedded in the monitoring and evaluation plan.	> Review how well the project is progressing – whether the harms and benefits are as expected and whether any unexpected issues have occurred that need to be addressed. > Consider any staffing issues–whether there are sufficient staff, or if training needs have arisen. > Consider whether collaborations (including with stakeholders) are working well. > Include ethical issues/considerations in your regular discussion with stakeholders and in intermediate reports. > "Capture" outcomes of discussions with stakeholders and hold debriefing sessions for staff at periodic intervals.
External ethical review processes: Submission to external review bodies	
Potential Steps	
External ethical review processes may not mandate intermediate or retrospective review of projects. If a review at one or both points is required, we recommend asking the review body for advice on how to proceed. The goals—and steps—are likely to be similar to those that are part of internal ethical review processes.	

1 Intermediate review may be carried out at designated time points (e.g., midway through the project) or at designated milestones (e.g., after the completion of pilot projects, or after recording baseline indicators). The nature and length of the project will guide the timings and process for intermediate review processes.

Retrospective - at the end of the project[1]	
Internal ethical review processes: Within organization and between stakeholders	
Goals	**Potential Steps**
The goals are to: • Quantify project impact: did it meet your stated goals; what harms were caused and were they justified against the benefits of the intervention; were there any ethical issues encountered that you did not anticipate? • Capture lessons learned: improve the design of future projects, monitoring, evaluation, and impact assessments. • Improve ethical decision-making and review processes within your organization.	> Thoroughly review all aspects of the project with respect to the goals in the left-hand column. > Feedback the results of retrospective review and impact assessment to your organization. > Feedback the results of retrospective review and impact assessment to all stakeholders. > Adapt plans for future projects in light of lessons learned. > Adapt ethical review processes in light of project learnings. > Publish your findings if appropriate; include your ethical review processes as part of the method in your publications; include ethical issues or considerations in your project impacts so that others can learn from your experiences.
External ethical review processes: Submission to external review bodies	
Potential Steps	
External ethical review process may not mandate retrospective review of projects. If a review at one or both points is required, we recommend asking the review body for advice on how to proceed. The goals—and steps—are likely to be similar to those that are part of internal ethical review processes.	

1 The 2015 RSPCA/LASA Guiding principles for AWERBs contains a chapter on retrospective and intermediate review of projects.


BACK

CONFLICTS OF INTEREST TOOLKIT

The term "conflict of interest," or COI, describes a situation where a person carrying out an action is—or is perceived to be—unable to make an unbiased decision (BMA, 2017). Bias or competing interests can threaten the integrity of a project and be detrimental to the well-being of its stakeholders.

Competing interests are often inevitable, particularly given the number of stakeholders (animals, owners/guardians, and communities) typically involved in projects. It is important to recognize a COI and, where possible, take steps to avoid it. Where competing interests cannot be avoided they should be stated openly, and steps taken to handle them responsibly.

IMPORTANCE TO AN ETHICAL REVIEW

A COI has the potential to compromise the decision-making, integrity, design, conduct, impact, reporting, or publication of the project. A COI can create serious tensions and compromise a person or organization's ability to act in the best interests of the main intended beneficiaries, or it can create undue/additional risks to the other stakeholders involved.

It is also worth noting that while some competing interests do not directly affect decision-making, they may nevertheless undermine the trust of certain stakeholders who perceive them as an undue influence.

ACTIONS TO TAKE AS PART OF A PROJECT

Actual or potential COIs should be recognized and avoided when possible. If they cannot be avoided, they must be managed responsibly, including full disclosure and justification regarding the nature and impact of the COI on the intervention and its associated stakeholders. If the COI of interest is serious enough that it poses a risk of significantly damaging the integrity of the intervention, consideration should be given to not proceed.

Identifying Conflicts of Interest

Ethical review bodies, funding agencies, and peer-reviewed journals may require you to identify, declare, and manage a COI. However, even if you are not required to identify a COI to proceed with a project, it is judicious to consider and manage potential instances where competing interests might affect your work. Doing this requires conscientious consideration prior to an intervention. It is particularly important to collaborate with other stakeholders to identify a COI, which requires consideration of all stakeholders' perspectives.

A COI may relate to particular individuals and their professional roles or responsibilities, such as a veterinarian or researcher. It may also exist at an organizational level. For example, an organization could exert undue influence over how a project is conducted at the local level due to that organization's partnerships or funders. Conflicts vary according to the type of interventions and the contexts in which they are undertaken, and they may be unique to a given set of circumstances.

Examples of COIs that may arise as part of field projects are listed below. The list is not intended to be exhaustive, but rather to prompt consideration of conflicts that might arise in your work.

- Personal gain through financial benefit, reputation enhancement, or professional advantage (glory-hunting!), where an individual's personal agenda is placed above that of the project and its intended beneficiaries.
- External influence or pressure (e.g., from certain stakeholders) unduly impacts particular protocols and imposes a different set of ethics or values over those of the local staff or community without appropriate advance consultation.
- Individuals wear more than one professional "hat," causing their duties or loyalties to conflict. For example, a veterinarian might run a clinical trial for a new drug in their veterinary practice, and the sponsor (e.g., a pharmaceutical company) provides a financial incentive to the veterinary practice. The goal of the study (trial) is to generate information (evidence) of the drug's safety and effect, which may cause harm to animals. The conflict of interest results from the professional responsibility of veterinarians to protect the welfare of animals under their care (do no harm) vs. the goals of the project (to generate data). This conflict has been discussed in regards to human medicine (Rao and Cassia, 2002).
- External factors or stakeholders influence the decision to publish results, the content of the publication, or the interpretation of the impact or findings of the project.
- Negative findings (e.g., what did not work and why it did not work) are not published based on influence of donor organizations, funding bodies, or other stakeholders. This might be because of fear of damage to reputation (not wanting to be associated with failure), fear of competitors gaining an advantage, or any number of other reasons.
- Pressure or incentive to publish findings drives project plans, which might not be justified based on welfare or other criteria (e.g., risk and types of adverse effects are already known).

(More information is available in National Audit Office, 2015; BMA, 2017; and University of Sheffield, 2019.)

Managing conflicts of interests

It is not possible to avoid all COIs, but it is necessary to be transparent about and actively manage them so that they do not unduly compromise the integrity of a project.

Below are general suggestions for managing COIs (see, e.g., National Audit Office, 2015; BMA, 2017; and University of Sheffield, 2019 for more information). However, given that COIs are often context-specific, it is imperative to identify management strategies within your organization and to discuss these strategies with stakeholders, if appropriate.

- Consult and adhere to relevant policies on COIs relating to your specific project, which may come from your organization, other stakeholders, academic partners, or funding bodies. A local ethical review body may have policies on managing conflicting interests that they typically encounter.
- If you don't have a policy that recognizes and manages COIs, consider creating one that addresses issues that are likely to be common and relevant to the nature and contexts of your work.
- Identify all real and perceived COIs that could damage the integrity and trustworthiness of the project.
- Take steps to avoid COIs where possible through modifying the design, conduct, and reporting of the project.
- Where possible, avoid getting involved in arrangements that conflict or are perceived to conflict with your obligations to the project.

- Disclose and justify real or perceived COIs, which may include making project information available to the wider public (e.g., individual donors), being transparent about your role(s) with owners/guardians of pets who are candidates for a project, and being clear about all the options that are available to owners.
- Report COIs in project outputs and publications.
- Report COIs when seeking consent or permission (e.g., include them in informed consent/permission dialogs).

CASE STUDY

When organizational policy is undermined by leadership and donors

An animal welfare organization is committed to improving the lives of dogs and cats in a Southeast Asian country through spay/neuter programs, a veterinary hospital, community outreach, and advocacy, among other activities. It has been successful at fulfilling its mission.

As is true for many organizations in less-developed regions, the organization was founded by expatriates living in the country, and the funding base is largely international. This support has been critical to the organization's success and facilitated rapid organizational growth through successful donor recruitment and digital fundraising. While the growth allowed for program expansion, hiring of qualified staff, and creation of protocols and procedures, policies were often ignored by members of the Board, who made decisions based largely on emotion and fundraising. This created some conflicts of interest.

For example, the organization has established policies regarding euthanasia, the return of animals back into the community following treatment, and shelter/hospital intake and capacity. These policies were established to ensure high levels of animal welfare in the shelter, as well as community buy-in. From time to time, however, Board members and major donors insisted on rescuing an animal themselves, and then dictating its treatment and outcome. More often than not they demanded that the animal be housed at the shelter indefinitely; this is in contradiction with shelter policy, which dictates that animals should be returned to their community so long as it is safe to do so.

A similar conflict existed when Board members or a donor requested that the hospital continue treating an animal with severe injuries, even though policy calls for euthanasia. Board members also had access to the electronic medical records and would demand that decisions be made about the animal's outcome based simply on photos of the animals, rather than the expertise of the medical staff. These actions and decisions led to shelter overcrowding, disease transmission, and compromised quality of care.

Further complicating matters is the fact that the organization's home country is largely Buddhist, where euthanasia and abortion (including spaying pregnant cats and dogs) are culturally taboo. Although this does not present a conflict of interest per se, it can complicate already emotionally challenging decision-making on behalf of animals in the organization's care.

The inconsistent decision-making, disregard for policies, and undermining of management eventually took an emotional toll on both staff and animals. Several members of senior management ultimately resigned as a result. In an effort to resolve these issues, a meeting was held between Board members and senior management to discuss the importance of adhering to shelter protocols. Eventually as the organization continued to grow, decision-making authority was largely put back into the hands of shelter management. With core policy decisions less vulnerable to inconsistency based on the influence of influential individuals, there are fewer conflicts of interest to manage.

As a final note, it is important to acknowledge that for some competing interests, declaring and justifying them may not be enough. If the COI relates to a particular individual, that person should consider standing aside from decision-making processes or the project as a whole. In addition, if the COI is severe enough that it poses a risk of seriously damaging the integrity of the project, consider breaking with relationships or stakeholders that create a potential COI, and whether it is acceptable to proceed at all with the project.

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BACK

DATA COLLECTION & USE TOOLKIT

Core to any study is the collection of data, and then the use of those data to test the study hypothesis/es. Certain field projects (e.g., a spay/neuter campaign) might not typically use "data" terminology, but instead describe data collection as monitoring, and data use as evaluation, which in combination are used to assess the project's effectiveness at achieving its desired impacts.

Regardless of what terminology is used, at their core the principles and purposes of collecting and using information are very similar. It is a scientific expectation, and also an ethical imperative, to have a means by which to evaluate the results of any intervention. Most projects, even those involving common or well-established practices (e.g., spay/neuter campaigns), have a novel component, often something as common as working in a new community. Anything "new" opens the door for questions about efficacy, safety, impact, risks, community acceptance, and myriad other variables. Data collection and use are essential to answer such questions. Consequently, regardless of how an intervention is named, all should have a sound plan for collection and use of data.

RELEVANCE TO ETHICAL REVIEW

Fundamental to the ethics of field projects is the balancing of harms and benefits. Though data collection serves multiple purposes in any project, one of its key functions is to estimate the extent of any harms or benefits; hence data is an essential part of ethical field projects. This includes planned data collection to measure expected harms or benefits; for example, using behavioral responses to application of a non-surgical fertility tool to assess how well animals tolerate the treatment. It also includes proactive methods of gathering evidence of unintended consequences; for example, easily accessible communication methods to report adverse events, or using qualitative data collection tools to assess both expected and unintended consequences for owners and other stakeholders.

Beyond the contribution data can make to answering ethical questions about the project, there are ethical questions inherent to the data collection itself. Ethical review (formal or informal) of a field project should cover questions relating specifically to the data collection process:

- Is the plan for data collection and use well designed? For example, is it clear what the data will measure? Is the method of measurement sufficiently sensitive? Is the sample size and composition sufficient to allow accurate and reliable conclusions to be drawn for the wider specified population? What analysis will be performed and what effect is it likely to be able to detect? Poorly designed data collection undermines the justification

for the whole project; a project should not be conducted if there is no means of evaluation, or if nothing can be learned from it.

- Do the data collection methods themselves have the potential to cause harm? If so, what steps have you taken to avoid or mitigate those harms? Have you applied reduction and refinement principals where appropriate (see Animals Toolkit)?
- Did you get meaningful informed consent/permission that covers not only the main purpose of the project, but also the data collection methods? For example, does the owner understand potential adverse events of the non-surgical fertility tool being tested and also that the study involves two blood samples being taken (see Informed Consent & Permission Toolkit)?

Ethics related to data collection from animals

Data collection methods should be as minimally invasive as possible while still accessing the data essential for testing the hypothesis. The ideal situation is a method that is so unobtrusive that the animal does not notice it is happening (e.g., behavioral observation in 'natural' habitat). Where invasive procedures (e.g., blood tests) are necessary, handling must be humane, aiming for the process to be perceived as positive by the animal rather than aversive, using rewards and prior habituation wherever possible; see page 59 for a discussion of road mapping to support refinement of data collection methods.

Ethics related to data collection from human participants

Although people may not be the principle subjects for the project, they are likely to be intrinsically involved as animal owners or guardians, as well as potential beneficiaries (e.g., if the project seeks to reduce public health risks). Consequently, data collection (through questionnaires, interviews, focus groups, street surveys/counts of dogs or cats, human-animal interactions, or behavioral observations) may involve human participants. Primary data collection by the field project may not be the only involvement of human participants; secondary sources of information may also include information collected from people (e.g., hospital records reporting dog bites or zoonotic disease incidence, municipal councils reporting animal nuisance complaints).

The ethics of human participation includes identifying and minimizing potential risks and harms, managing personal and sensitive data responsibly, and adhering to legal and recognized principles for protecting human subjects.

Potential harms for human participants

In addition to physical and severe psychological harm, people can suffer from lesser harms (e.g., embarrassment or annoyance) associated with being asked to reveal personal information. Potential harms to be mindful of when gathering information from people include:

- Discomfort or stress when being interviewed or included in focus groups.
- Risks to participant's personal or social standing, particularly if there is a breach of privacy that reveals personal values, beliefs, or behaviors.
- The adverse effects on owners or caretakers of revealing information that relates to illegal or deviant behavior. Your questions may require participants to reveal illegal acts (e.g., is your dog vaccinated against rabies? Does your dog roam in public areas without your supervision?). Alternatively, people may reveal information to you (about themselves, their family, or their neighbors) that you had not anticipated (e.g., their neighbors deliberately abandoned an animal because they were no longer willing or able to care for it).
- The effects on participants of revealing information that is not considered in line with social norms (e.g., caring for dogs and cats in locations where cultural or religious beliefs lead other members of the community to consider this practice as something to be feared or avoided).
- Some human participants or community members are more vulnerable to harms than others. Particularly vulnerable populations include children; individuals who are disadvantaged and not sufficiently empowered to refuse to participate; and displaced peoples/undocumented immigrants, who may be fearful of being reported to authorities.
- The way in which collected information is presented and reported to the wider public may cause discomfort or embarrassment to the community because it reveals what they think or feel about dogs or cats that may not be typical of social norms.

Managing personal and sensitive data

Those who collect information from people have an ethical obligation, and potentially a legal duty, to protect privacy and confidentiality. The term "data protection" is used here to refer to legal obligations on what information can be collected from people, how it can be stored and used, and the responsibility of ensuring people can understand what is being collected and why. Some locations have no legal equivalent of data protection regulations, while it may be more common or harmonized in others (e.g., General Data Protection Regulation in the European Union). It is important that you identify and follow national, regional, and local laws, regulations, and codes on data protection. Some of the data gathered from people will be covered by data protection regulations, and breaches to those regulations could incur a penalty. Important terms relating to data protection are described below. Please be advised that legal regulations may include different definitions of these terms that must be followed.

Personal data. Relates to a living individual who can be identified through the information we gather. This could be directly (e.g., through their name, address, phone number, or email address) or by combing sources of information (e.g., Global Positioning System [GPS] data, plus gender- or age-related information recorded in a questionnaire, combined with names and addresses gathered from electoral roles that can be readily accessed through public records). If you were to record human participants using audio or video devices during interviews or focus groups, even if they were not named in the recording, they could be identified by others who recognize their voice or appearance from the sound or visual images.

Sensitive data. Refers to personal data that consist of information that reveals a person's racial or ethnic origin, political opinions, religious beliefs, physical or mental health conditions, or sexual orientation; it may also reveal the commission or alleged commission of any offense (has the person broken the law, not followed local regulations?). These types of sensitive information could be used to discriminate against individuals and therefore should be treated with greater care (kept private and confidential) than other types of personal data listed above.

Sharing data. Given that many field projects involve multiple stakeholders, it is common to share data among individuals, organizations, and locations. The individuals collecting data may differ from those who analyze and report it. Data protection regulations may place obligations on individuals regarding the sharing of data to third parties (those that are not associated with collecting the data), and this may include putting agreements in place between individuals and organizations to ensure data protection regulations are followed by all parties even though local regulations do not exist.

Helsinki principles – ethical principles for protecting human subjects

The Declaration of Helsinki was developed by the World Medical Association as a set of ethical principles regarding medical research on humans. Its primary purpose is to promote and protect the health, well-being, and rights of patients. The Declaration's fundamental principles more broadly form the cornerstone of human research ethics and are often referred to by other research codes of practice. Journals may require a written declaration from authors stating that they followed the guidance outlined in the Declaration of Helsinki if their research involved human subjects (e.g., through interviews, focus groups, or questionnaires).

All of the Helsinki principles are relevant when including human participants. However, Appendix 1 includes principles that are particularly relevant when planning a field project involving both animals and humans.

ACTIONS TO TAKE AS PART OF A PROJECT

Below are actions that those designing and/or implementing a project can take to ensure that data collection is conducted ethically from the standpoints of both the animals and humans directly and indirectly involved in the study.

Road mapping to identify harms

Any direct interaction with animals in order to collect data needs to be explored for the potential to cause harms. 'Road mapping' involves breaking down the interaction into its composite steps, making the exploration of potential harms more thorough. Where potential harms are exposed, options for refining or replacing that step should be considered. Where there are no other options, and the potential harm is considered justified by the anticipated benefit, there should be a process for monitoring whether harm occurs and what was done in response.

CASE STUDY

Funder requires baseline data collection before providing project support

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Prior to considering a request to support a humane dog population management intervention in two European municipalities, a potential donor requires that the local nongovernmental organization (NGO) seeking funding conduct monitoring and evaluation, including baseline measures of dog population numbers and density.

This approach is new and unfamiliar to the local organization, as are the communities that are the focus of the study, but the organization makes a best effort to gather these baseline data. It begins by conducting a street survey of roaming dogs, and then a survey of hundreds of households in the designated intervention area, making a point to select a representative sample.

NGO staff, who are not from the specific communities of focus but are from the country where the work will take place, conduct the surveys. Surveyors enjoy counting dogs on the street; they readily interact with the animals, photograph the dogs on their phones, and engage with the local community when asked what they are doing (this is the first opportunity for community residents to learn about the potential intervention).

Meanwhile, the sizeable household survey asks people about their knowledge, attitudes, and practices towards dogs (both those they own and roaming dogs observed on the streets). It reveals that many individuals provide some form of care to dogs, while many others feel that dogs are a nuisance and the "dog situation" is getting worse—indicating that the community is somewhat polarized. It is also discovered that local authorities are not fully in support of the goals of a humane dog population management intervention—raising questions of how to collaborate with the local authority before taking even initial project steps (and if this is not possible, the hard decision must be made whether this is the right time or place for the program).

Although the NGO ultimately does not receive funding to support the desired project, it did several things well. Among them, it conducted the requested baseline data; calculating roaming dog numbers and evaluating resident knowledge, attitudes, and practices. (Credit also goes to the donor agency both for requiring baseline monitoring and providing financial support for it.) It also selected positive, enthusiastic surveyors, who were citizens of the country and engaged with and responded to community members.

Data management plan/monitoring & evaluation plan

A data management plan should make explicit what is being measured, by what method, how and where data will be stored, and who is responsible for data collection and storage. For field projects, this information may be more commonly presented in a monitoring and evaluation plan. Although field projects do not always include explicit plans for data storage, planning for this detail will be particularly important when engaging with human participants in countries with strict data protection protocols.

Communication methods

In recognition of the diversity of participants in field projects, establishing suitable forms of communication is essential. This may include "hotline" phone numbers, consistently monitored email addresses, social media groups (e.g., Facebook), groups using messenger apps for smartphones (e.g., WhatsApp) or recognized "go-to" people in the community (e.g., official community leaders) who have been prepared to act should a problem arise.

Selecting a method of communication should be done in collaboration with representatives of the people who will be engaged in communication to ensure that a familiar and convenient method can be selected.

Such communication can be used for data collection as part of planned monitoring; for example, owners might be asked to send photos of injection sites every day for two weeks. However, predetermined communication methods should also be established to report unexpected harms. In field projects, such problems may occur without immediate supervision, or access to mitigating measures such as veterinary assistance may be delayed; hence the available communication method must be fast and reliable. This requires communication channels to be monitored constantly, and usually involves multiple people to share this monitoring and response role.

Participatory monitoring

Researchers involved in the field projects will have a detailed understanding of the project's aims and ethical considerations. It is important to recognize, though, that this is one person's, or group's, perspective. Efforts should be made to engage other stakeholders, including animal owners/guardians and the broader community, in the data collection and evaluation process. This establishes a wider understanding and appreciation of the project but also opens up the researchers to the perspectives of others impacted by it.

Evaluation events

Data analysis, interpretation, and reporting are a natural part of all experimental studies. By nature, field projects have a wider impact on the communities in which participants live than do experimental studies. It is important to plan for how to share project results and also capture the perspectives of people in the community interested in the project findings and impact. Keep in mind that the timing of and location for any event designed to share results and garner feedback need to be convenient for and accessible to the community.

Pilot and evaluate before roll-out

Piloting field projects with a small and well-monitored sample is beneficial for many reasons, not just related to the ethics of data collection. However, with this particular perspective, such pilots can be a good opportunity to test data collection methods for further refinement or replacement to reduce potential harms, and to evaluate whether the process of informed consent/permission was sufficient for the owner/guardian. In addition, the full process of data collection, storage, and analysis can be tested to check the robustness of the experimental design and any other ethical questions, such as data protection.

REFERENCES

World Medical Association. (2013). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Retrieved from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

APPENDIX 1

Select adapted *Declaration of Helsinki* principles with application to data collection and evaluation

The Declaration of Helsinki includes principles that form the cornerstone of human research ethics; in combination they are designed to protect human subjects taking part in research. Although the nature of field projects involving animals would tend to limit the harms posed to humans, there is no question that humans (owners, guardians, community members) still face risk. The following adapted Declaration of Helsinki principles were selected because they have particular relevance to field projects with both animal and human stakeholders, and the nature of field projects might impact how these principles are implemented in the context of data collection and evaluation.

Relevant adapted *Declaration of Helsinki* principles	Practical applications in field projects
Continual monitoring Continual evaluation of safety, effectiveness, efficiency, accessibility and quality is required.	Data collection relating to identified potential harms needs to be conducted at a frequency likely to detect harms followed by prompt and proportional response; this response may require transport of animals or personnel. An accessible communication system, instituted with the agreement and support of community representatives, should be constantly monitored in order to detect harms outside the planned data collection.
Protect human research participants Research participants have rights that should be protected, including dignity, integrity, self-determination, privacy, and confidentiality of personal information.	Protecting human participants' rights to make decisions about what information is collected about them and their animals, as well as how that information is used, should include seeking prior informed consent/permission. Participants have the right to control personal and sensitive information collected about them; this means that those implementing the project should store data in a way that allows removal of a participant's individual data if they request to no longer take part in a project. All participants have the right for the information they provide to be kept private (limited to selected individuals that collect and/or process the raw information, for specific purposes) and confidential (not shared without their prior permission). Consider whether you need to collect personal information, or whether data can be anonymous.
Consider the ethical, legal and regulatory norms and standards for research involving human participants in their own countries as well as applicable international norms and standards.	Do your homework when it comes to finding out what ethical review processes you need to follow alongside local regulations that oversee "research" on humans. Check what data protection regulations exist and follow them in your data management plan.

Relevant adapted *Declaration of Helsinki* principles	Practical applications in field projects
Risks, benefits & burdens Research may only be conducted if the importance of the objective of the project outweighs the risks and burdens to the participants. Assess the predictable risks and burdens to research participants, ahead of time.	Use harm-benefit analysis to weigh the risks of harm to human and animal participants against the benefits to the project. If the risks outweigh the benefits, even with further refinements, you should not proceed. Re-evaluate this on a regular basis using data, as conditions in the field are likely more variable than a laboratory setting; be ready to halt the project if the balance tips towards harms. Proactively gather and consider the perspectives of all stakeholders and how they may be affected; the number of relevant stakeholders for a field project is likely greater than for a laboratory study. Ideally conduct a pilot project with in-depth evaluation and adaptation of project design ahead of full project launch.
Vulnerable groups and Individuals Some groups and individuals are more vulnerable than others and as a result may have an increased likelihood of incurring additional harms or burdens. All vulnerable groups and individuals should receive specially considered protection.	Do your homework! Understand the nature of the community in which you will be working by undertaking scoping research ahead of finalizing project design (e.g., community mapping, stakeholder engagement). List criteria that may indicate individuals or communities are vulnerable and think about how you will identify vulnerable individuals in the field (see Informed Consent/Permission Toolkit). Potential vulnerable individuals, groups, or communities should be identified in advance and given special consideration during ethical review (whether the ethical review process is formal/ institutional or not). This may include adding suitably qualified, experienced individuals with the necessary expertise to impartially advocate for vulnerable groups or individuals during ethical review.
Research design Research involving human subjects must conform to accepted scientific principles (good experimental design), be based on a thorough knowledge of the scientific literature, and all other relevant sources of information (e.g., safety and efficacy data etc).	Do your homework! Follow recommended guidelines on good practices for research (e.g., monitoring, evaluation, impact assessment). Where appropriate, perform a literature review, seek advice on experimental design (to ensure you get valid and reliable information), and/or consult a statistician for assistance with data analysis. Note that subjects recruited for field projects are likely more variable in their characteristics, and therefore responses, than those used in laboratories; this may increase required sample sizes.

Relevant adapted *Declaration of Helsinki* principles	Practical applications in field projects
Research ethics committees The research protocol must be submitted for consideration, comment, guidance and approval to the appropriate and competent research ethics committee before the project starts.	Do your homework! Check local regulations for ethical review. Identify time requirements, processes, and costs associated with submitting the project for evaluation to the review body. You will be expected to follow the recommendations given by the review body before you start collecting data. Many organizations do not have easy access to external ethical review bodies; hence what is feasible versus good practice might need to be considered. Use the toolkits to help identify, reduce, and mitigate harms to research participants and develop internal review procedures as best you can.
Privacy and confidentiality The researcher must protect the privacy of research subjects and the confidentiality of their personal information.	Identify if you are collecting sensitive and personal data, and keep in mind that seemingly innocuous actions could have unintended consequences (e.g., taking the GPS location of a household or describing an animal could be sufficient to identify someone). Do you need to collect those data? Or can data be anonymous? Develop a data management plan that helps to protect privacy and confidentiality of human participants. Understand the legal aspects of confidentiality and privacy.
Informed consent Documented informed consent is required and must be voluntary and freely given.	Aim to obtain and document informed consent/permission. Consent must be freely given – consider when consent is asked, does the person have time and space to feel both informed and free to decline? Field projects may involve busy periods when obtaining consent/permission is difficult (e.g., central point vaccination campaigns). Debriefing may also be warranted as a part of the consent process. It occurs at the end of the research activity (at the end of an interview, at the close of a focus group, at the end of a questionnaire). It provides participants again with a full explanation of the study and any other relevant background information and gives them an opportunity to withdraw consent before their data are processed further. Such debriefing of participants in a field project may require time to travel/search for participants.

Relevant adapted *Declaration of Helsinki* principles	Practical applications in field projects
Informed consent continued...	
Human participants must be informed of the right to refuse to participate in the project and the right to withdraw consent to participate at any time without punishment.	All participants should be informed of their right to refuse to take part in questionnaires, interviews, focus groups, etc., and their right to withdraw at any point without explanation or penalty, even if the participant willingly participated in the initial stages and provided informed consent/permission. The debriefing process should also include repeated information of the right to withdraw and for their data to be removed from analysis. Field projects will need to have an accessible and constantly monitored communication method available for participants to contact them if they wish to withdraw.
When asking for consent, special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. You should take steps to ensure the human participant has understood the information given to them.	Pilot and adapt the informed consent/permission dialog and method of recording consent to local conditions to ensure it is meaningful and that the participant has understood the information provided so they can make a decision about whether to participate.
Where possible seek freely given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.	Full written consent may not be feasible in field project conditions. An alternative is a consent dialog with human participants, ideally witnessed and then recorded; e.g., a tick box on data recording sheets that record that consent was verbally given by research participants, following the consent dialog.
Human participants should be given the option of being informed about the general outcome and results of the project.	It is good practice to give people information about how to find out about the results of the project, should they wish to know, and a timetable of when the results of the project are likely to be available and from where. If this is not feasible, let participants know that this is the case in the informed consent dialog.
Publication and dissemination of results	
Reports of research not in accordance with the principles of the Declaration of Helsinki should not be accepted for publication.	You may risk having a publication rejected by peer-reviewed journals if you have not demonstrated that you have followed and applied the Helsinki Principles when including human participants in monitoring, evaluation, and impact assessments.


BACK

INFORMED CONSENT AND PERMISSION TOOLKIT

CONSENT FOR HUMAN PARTICIPATION IN A PROJECT

Ethical review of studies involving human subjects gives extensive weight to the process of obtaining prior, voluntary informed consent from study participants. Informed consent is based on the ethical principle that every person has the right to self-determination and autonomy. It means that individuals should never be coerced, persuaded, or induced to take part in research (Green & Thorogood, 2014). Obtaining meaningful informed consent is a process that requires an understanding of five essential elements (Wilkinson et al., 2008; Beauchamp & Childress, 2013):

1. The competency of the individual to understand and decide.
2. The transparent disclosure of information in sufficient detail and in such a way that the person can understand it.
3. The understanding of the information (including the risks and benefits) and what that means for them (or the animals they care for) now and in the future.
4. The person decides voluntarily without influence, coercion, or manipulation.
5. Consent is documented (either in writing or witnessed and recorded).

The principle of informed consent initially evolved in the context of biomedical research. The Nuremberg Code, completed in 1947, was the first formal international document with ethical principles for research on human subjects, including voluntary participation and informed consent (Shuster, 1997); in 1964, the World Medical Association released the Declaration of Helsinki. Additional pivotal documents focusing on informed consent in human biomedical research have been developed within individual countries (e.g., the Belmont Report [National Commission, 1979] in the U.S.).

The ethical imperative for informed consent is also written into the codes, rules, and policies of many professional associations, government agencies, and universities. It extends well beyond biomedical studies and into social and anthropological research involving human subjects (Resnik, 2015).

Given the focus of this resource, combined with the availability of publications and guidance on the topic of informed consent in human (social) research, we do not discuss the topic in detail in this toolkit. We do emphasize, however, that informed consent is an essential component of collecting any personal human data. If your project will collect any data from people about themselves and/or their animals, you must have individuals' informed consent to do so.

In addition, many projects will capture images and stories from a community, which is a form of "taking" property or information from the community yet sometimes overlooked as such. Photography and storytelling should be conducted with the utmost respect for human dignity and the full and informed consent of community members (further details are in the Communities Toolkit). Note, as well, that your work may be subject to country-specific regulations (for example, the European Union General Data Protection Regulation [2019]).

More information on the topic of informed consent in human research is available in the Further Reading section at the end of this toolkit. In addition, the specific topic of obtaining informed consent to depict communities as part of a project (e.g., through capturing and sharing images and stories) is discussed in the Communities Toolkit.

PERMISSION FOR ANIMAL PARTICIPATION IN A PROJECT

Now let's turn to non-human project participants. What happens when the study participants are dogs and cats? How do we protect their rights, interests, welfare, and autonomy? They cannot give informed consent themselves, nor can owners or guardians offer informed consent on their behalf (though animals can certainly dissent through behavioral response to an interaction or treatment).

To begin to answer this question, we can look at ethical guidelines for studies involving humans who cannot offer informed consent, such as children or adults with compromised intellectual capacities. These populations receive special consideration by researchers and research ethics committees (CIOMS, 2016).

Children participating in a study can often provide "assent," which refers to an affirmative agreement to participate (i.e., "assent" is not simply the absence of dissent). Assent presumes that children are capable of understanding the nature and implications of participation, even if they are not able to evaluate all the information in such a way that would allow them to formally "consent." Depending upon the child's age, the ethical review process may require that assent is received along with permission from a legally authorized representative or proxy (CIOMS, 2016).

Unfortunately, assent cannot reasonably be used in studies involving dogs or cats. Therefore, in practical terms, we are left with "permission" from the dog or cat's proxy (the guardian) being the means by which to gain approval for an animal to participate. This is common practice with dogs and cats—if your pet undergoes a procedure at the veterinarian, you will likely sign paperwork giving permission for that procedure to be performed. However, a procedure intended to directly benefit the health of that individual animal differs from a study in which benefits are not guaranteed, or one where benefits would be realized by future generations of animals. This brings us back to our core question: how do we utilize permission in a way that considers the autonomy of pet and/or community animals as study subjects?

This toolkit seeks to provide guidance on how to answer this question as part of studies or projects in which dogs or cats take part.

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IMPORTANCE TO ETHICAL REVIEW

It is widely accepted that obtaining informed consent from human participants prior to beginning a study is an ethical requirement. Participants must know what they are agreeing to. In an ideal world, we could do the same for dogs and cats; it would be wonderful to inform animal participants of the risks and benefits and know that they agreed to them. Since we cannot do this with cats and dogs, the best option is to obtain permission from those who speak on behalf of individual animals, similar to adults speaking on behalf of their child. It is arguably the closest we can come to considering the animal's perspective, acting in that animal's best interest, and ensuring that the animal's physical and psychological needs are being met (see, e.g., the Five Animal Welfare Needs in the Animals Toolkit).

ACTIONS TO TAKE AS PART OF A PROJECT

The following points may help to guide planning discussions and decision-making, and inform protocols around seeking and obtaining permission, that inform project design and implementation:

- For what are you seeking permission? What is the nature of the risks or benefits to study participants?
- From whom are you seeking permission? Owners, keepers, caretakers, or a community? From whom can you seek permission for animals who lack a single guardian? How does the community recognize ownership or guardianship? What is the nature of the risks or benefits to owners, guardians, or communities when they consent (or not) to inclusion of their animals in the study?
- What factors impact the dialog between guardians and those implementing the study? How will you obtain meaningful permission?

What are the limitations or challenges with meeting the essential elements of gaining permission? How will you tailor your dialog to reflect the likely risks or benefits to animals or humans? How will you tailor your dialog to respect the local community and contexts in which the research would take place? What are the uncertainties to understanding risk, and benefits of the project, and how will you communicate this?

- How will you document guardian permission in a way that upholds ethical standards and accommodates community norms and individual guardian capabilities (e.g., language barriers, (il)literacy)?

Common challenges to gaining permission

There are a number of hurdles that could be encountered when seeking a guardian's permission for an animal to take part in a study (it is worth noting that several of these hurdles also apply to obtaining informed consent for human participation in a study). This section is structured to describe common challenges to obtaining permission and strategies to address them:

The capacity of the guardian to understand and give permission

In order to provide permission, the person giving it must have the capacity to provide permission. Capacity broadly describes an individual's ability to "do something" successfully: to perform a task, make a decision that reflects their values and beliefs, identify preferences, and identify different choices (particularly related to risks, burdens, or benefits associated with different courses of actions). It is incumbent upon those implementing a study to ensure that guardians are capable of providing permission.

Toward this end, information about a study must be shared in a transparent and sufficiently detailed manner. It should be presented in a way that allows an individual to understand and process it. This places an obligation on those implementing a study to accurately present the likely risks, benefits, or burdens of the proposed course of action. Where there is uncertainty regarding the ability to do this, that uncertainty must be disclosed. This disclosure will also help to avoid "deception"—intentional or unintentional acts that hide truthful information, resulting in an individual being manipulated to act in a certain way.

The way in which information is communicated (e.g., verbally; in writing; through use of diagrams, props, or acting out scenarios), and the context (e.g., location, environment,

what is happening around the individual) in which information is given, can influence an individual's capacity to understand and process information. As part of the dialog surrounding permission, a guardian should have opportunities to ask questions and seek further information/clarification. The person seeking permission also has an obligation to confirm that the guardian understands both the information and the choices being presented.

An individual's capacity to grant permission can fluctuate over time—we may make different decisions about the same things in different contexts, for example, or change our minds in light of experience. The dialog should therefore reflect and convey to individuals that they have the right to change their mind; to withdraw their permission at any time and without penalty. (In addition, depending upon the level of risk involved to individuals and their animals, it may be prudent to continue to check at prescribed intervals that their original decision to give permission to a course of action still holds.)

In sum, the dialog should aim to:

- Evaluate an individual's capacity to understand and process the information.
- Prepare individuals to make a decision, specifically letting them know that a decision is expected to be reached and authorized.
- Be mindful of information overload and unfamiliar terminology.
- Use appropriate decision aids to help foster understanding.
- Ensure that individuals understand the information provided, their options, and the consequences of those options as best as possible.

Any deficiencies in the communication process are likely to impact the individual's understanding and capacity to provide meaningful permission. To this end, it is essential to account for language barriers when planning a study. This means ensuring that those who are discussing the study with guardians are doing so in the guardian's language of choice.

Competency is an underlying tenet of being capable of providing permission. Competency is often associated with an individual's cognitive abilities. When seeking to obtain permission for an animal's participation in a study, it is essential to ensure that the guardian is competent to give permission.

In a "real world" context, this requirement can present some hurdles. For example, in some communities, dogs commonly belong to children, or the child is tasked with bringing them to participate in a project (commonly a rabies vaccination or spay/neuter campaign). Per the norms of ethical research, children cannot grant consent for their own participation in a study, and thus are not able to grant permission for their animal's participation. And yet, precluding children from authorizing their animal's participation in a study could dramatically reduce the number of animals reached, and at the same time undermine support for the study if excluding children goes against local norms.

It is important to do whatever extra work is required to make an informed decision about how to proceed (or not) with the proposed study. For example, with the example of children, you might explore the following: What is the legal age of consent in the country?

Are children asked to make other important decisions, and if so, at what age? Are there any rites of passage or ceremonies in the culture that convey more responsibility to a child? Are the risks simply too great and thus the study must not take place unless an adult can provide permission? These possibilities need to be accounted for when considering how dialog will be structured to protect the interests of human and animal study participants. Proper planning (including reaching out to local organizations, contacting other organizations doing similar work, and engaging help of community members) can help achieve informed permission in a complex environment.

Avoiding undue influence

It is important to ensure that a guardian is able to make a decision without controlling influences (e.g., coercion, persuasion, or manipulation) from external sources. External sources could be another person who has power or authority, or certain conditions, such as financial incentives.

The people tasked with gaining permission may intentionally or unintentionally influence the process. Field studies might include situations where power differentials compromise the principle of freely giving permission. For example, "gatekeepers" from within a community are often integral to a project's success. By definition, gatekeepers control access to the place where a project or study is taking place, or to potential participants. This control can be formal or informal (Green and Thorogood, 2014). Gatekeepers may aid in recruiting groups or individuals that are otherwise hard to reach or help to provide information to individuals about the study. Gatekeepers could be village elders who control access to community members, for example, or teachers whose support is needed to gain access to children (e.g., for educational interventions to reduce dog bite incidence).

Although gatekeepers can be essential to study success (e.g., helping to access animals), they can also have undue influence on the selection of research subjects, types of questions asked, study design, or subsequent presentation or reporting of results. Some individuals may not be sufficiently empowered to decline to take part in a study, or decline their animal taking part, if a community leader has agreed to and encouraged participation. Although the use of gatekeepers can be a great asset, it should be recognized and justified as part of an ethical review, with steps outlined to ensure that participation of humans, or permission for their animals to participate, is truly voluntary.

Definitions

Coercion: the intentional act or practice of force (threat or harm) to control another person.

Persuasion: the intentional act or practice of convincing someone to do or believe in something.

Manipulation: the intentional act or practice of several forms of influence that are neither persuasive nor coercive; for example, the deliberate manipulation of information to modify peoples' understanding of a situation that alters their decision to act (e.g., withholding information or exaggerating information such as risk, benefits, or burdens).

The role of gatekeepers

Animal Balance supports island communities in implementing humane dog and cat population control strategies. When Animal Balance conducted a Mobile Animal Sterilization Hospital (MASH) clinic on American Samoa, it approached church leaders to help encourage community participation in the clinic. The leaders' presence at the actual MASH clinic was not requested, however, to encourage participants to freely give permission for their animal's sterilization surgery without undue influence.

The study team itself might also create undue influence, oftentimes unintentionally. If there is a power, educational, or economic differential between the persons implementing a study and community residents, the latter might feel obligated or unreasonably motivated to participate or permit their animals to do so. It's also important to consider what the people implementing the study represent given their country of origin, their race or ethnicity, and the historical context, among other factors. One strategy to combat this undue influence is to hire local residents to facilitate the project.

Finally, finances can create undue influence. It is important to ensure that the use of incentives or compensation do not override the principles of meaningful, freely given permission. This could include financial incentives for participating in research or access to services that wouldn't ordinarily be available. Specifically, enrollment in a clinical trial or field study of a new practice or technology, where treatment is free, may be an incentive for owners to enroll their pets to participate on the chance that it has some therapeutic benefit for the animal that the owner would not otherwise be able to afford. This does not preclude use of incentives or compensation to help recruit study participants, but simply means that they should be given careful consideration in the processes of study design and ethical review.

Who is the guardian?

With free-roaming animals, it may be very challenging—or even impossible—to identify an animal's guardian (i.e., the person who is best positioned to advocate on behalf of that animal) to get permission for that animal to take part in a study. This does not mean that an animal lacks a guardian, but rather that additional effort and potentially creative thinking must be used to identify the guardian to gain permission.

In some cases, a community will collectively care for animals by providing food or shelter, for example, but there is no single guardian. In such instances, those implementing a project must not assume that they have the right to provide treatment without permission. Instead, it is important to seek out people who know the animal and ensure that those individuals give permission for treatment.

Keep in mind, as well, that when a roaming animal does not have a single owner or guardian, it is likely technically "owned" by a governmental body. Consequently, it is important to ensure that the program has permission from the appropriate governmental entity to proceed (depending on location, this could be municipal government, local government, village authorities, or others).

CASE STUDY

Seeking informed permission for study participation in a complex field environment

In 2016, the Alliance for Contraception in Cats & Dogs (ACC&D) conducted a study of a "21st century" ear tag in a population of free-roaming, owned dogs in Kenya. The organization is exploring different methods of marking and identifying dogs and cats who have been sterilized without surgery, and more broadly dogs who have been vaccinated against rabies. Since neither of these procedures requires anesthesia, the marking method cannot, either. The purpose of the study was to evaluate application of the tag in conscious animals, and the tag's durability in a real-world context. After careful evaluation of multiple potential study sites, the study took place in conjunction with a rabies vaccination campaign in a Maasai community in rural Kenya.

The rabies vaccination team hired community representatives as part of the rabies vaccination campaign to notify dog owners about the upcoming opportunity to get a free vaccine to protect their dogs against rabies. ACC&D created a short description of the ear tag study, which was translated into Swahili and Maasai, to include in this outreach. The description was made into fliers and distributed by community representatives (see the English version of the flier at right).

On the day of the vaccination campaign and tagging study, a tagging team member (Kenyan veterinarian or member of the community) approached adult guardians—no children—to ask if they would be interested in participating in the study. A trilingual English/Swahili/Maasai speaker was tasked with explaining the study to the guardian in simple but substantive terms. In an ideal scenario, this would have reiterated material that guardians had had an opportunity to see in advance. However, the advance outreach did not take place in the same area where rabies vaccination took place on the day of the tagging study. This meant that guardians learned about the tagging study for the first time on the day that it took place. Due to the high level of illiteracy in the community, only verbal permission was obtained.

The process of recruiting participants and obtaining permission for participation faced several hurdles. Many guardians actively sought an ear tag for their dog. How wonderful that there was such community interest! However, this overwhelming interest prompted questions about why people wanted the tag (for identification, status symbol, visual appeal?) and the influence of community outsiders (Kenyan veterinarians and an American researcher) on peoples' interest.

Young children (under the age of 16-18) were declined per study protocol and concerns about their capacity to grant permission. So, too, were adult guardians of dogs who showed anxiety or fear when receiving a rabies vaccination—a decision made to isolate a dog's response to the ear tag from other stimuli or handling. It was unfortunate to disappoint enthusiastic guardians, but efforts were made to explain the rationale and avoid causing personal offense.

The field environment for the study was not conducive to extended conversation between a study representative and guardian. There was a lot of activity and abundant intact dogs in a concentrated space, many of whom were not comfortable being leashed. The circumstances were such that although the study representative had a written description intended to be read to each guardian, there was pressure to expedite the process. Even so, a best attempt was made to ensure that the guardian had complete information before permitting their dog to receive a tag, verbal permission was documented and contact information was recorded for follow-up.

LAIKIPIA RABIES VACCINE CAMPAIGN

FREE RABIES VACCINE FOR YOUR DOG

Bring your dog on 2nd or 3rd September for a free rabies vaccine! It is safe for your dog and will protect him from this deadly disease.

Your dog can also join a study of an earring (*photo at right*) that shows he was vaccinated against rabies this year. You can choose if you want your dog to have an earring; **it is not required for a rabies vaccine**. If he gets the earring, he will also receive a microchip the size of a rice grain under the skin. This will show that he belongs to you and he has been vaccinated.

If your dog gets an earring, he will be part of a study lasting 2 or more years. You must allow our veterinarian and field assistants to visit your dog to check the earring.

If there are problems with the earring, the study will pay for medicine or treatment. If you have questions, or if your dog has a problem with the earring, or if you want the earring to be removed at any time, call [redacted] at [redacted].

When seeking permission for a community animal, it is possible that guardians will disagree on the animal's participation. In this case, whether or not consensus is necessary depends in part on the risk to the animal. If there is a high social value and minimal risk (e.g., rabies vaccine), it may be justifiable to proceed (see next page). However, it is always important to fully weigh arguments against proceeding.

Working within your environment

This ethical guidance document defines "field" very broadly—i.e., it is any space outside a laboratory. However, some studies will take place quite literally in "the field": in neighborhoods, streets, parks, or other spaces that may not be conducive to a dialog that would satisfy typical requirements for obtaining permission. Certain field contexts will present particular challenges with regard to granting permission for an animal's participation in a study.

Permission should be sought in an environment that permits dialog about participation in a study. This would ideally be a controlled environment that allows private and unrushed conversation. Field conditions can be anything but! Animals may not be accustomed to being confined in a cage or by a leash, and their behavior reflects that, or they might be brought without a leash or carrier. A sterilization campaign will draw multiple intact animals and the associated challenges of safely managing these individuals. Owners or guardians might not be waiting with their animals in an organized fashion.

These possibilities need to be accounted for when considering how dialog will be structured to protect the interests of human and animal study participants. Proper planning can help achieve informed permission in a chaotic environment. For example, can you enlist volunteers to help answer participants' questions? Can you vaccinate dogs in the morning and cats in the afternoon? Can you reach out to organizations doing similar work to ask for tips?

Documentation of permission

A guardian's permission for the animal to take part in a study should be documented. This means having a record of the following:

- The information conveyed to the individual (ideally standardized language to ensure that all guardians receive the same information).
- The willingness of the guardian(s) to follow a course of action.
- Proof that the approved process of obtaining permission was followed.

- The individual's awareness of recording verbal or written permission to include an animal in the study.
- Authorization by the individual for that chosen course of action.

Documentation can take different forms. The more typical would be written permission by the individual (e.g., signature on a permission form). If circumstances do not allow for this (e.g., a guardian is not literate), an alternative option is to have written verbal permission after listening to a statement that outlines the information above. Authorization would then be recorded by the person seeking permission (e.g., by checking a box on a permission form or questionnaire).

Are there instances when permission can be ethically waived?

There is no single, definitive answer to this question. However, the Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO), offers a perspective on human studies that might be applied to animals. The guidelines state that a "research ethics committee may approve a modification or waiver of informed consent to research" on three conditions: 1) the research would not be feasible or practicable to carry out without the waiver or modification; 2) the research has important social value; and 3) the research poses no more than minimal risks to participants (emphasis added) (CIOMS, 2016).

How would this apply to studies with animals? There are limited instances where a research ethics committee could justify treating an animal without permission from a guardian. One example might be a rabies vaccination campaign, in which vaccinating a dog presents minimal risk and high social value and therefore it is arguably ethically permissible to vaccinate a free-roaming dog if a guardian can't be identified to provide permission. "Minimal risk" and "high social value" involve subjectivity, of course, and the interests and perspectives of different stakeholders should be accounted for when considering what, if anything, could be undertaken without guardian permission.

SUMMARY

Obtaining informed permission for an animal's participation in a study is essential.

The process may require creativity and flexibility to ensure that key tenets of an ethical process are met:

- Ensuring the guardian's capacity to understand and give permission.
- Avoiding undue influence.
- Ensuring that the guardian(s) are appropriately identified.
- Working within the realities of the field environment.
- Documenting permission.

CASE STUDY

Manu Mitra

In 2016, the government of Kathmandu Metropolitan City (KMC) partnered with a local organization, the Jane Goodall Institute Nepal, to launch a program called "Manu Mitra," which translates to "friend of human." The goal of Manu Mitra was to establish a community-led humane dog population management program, engaging the community in the care of dogs and building on the foundation of compassion in Nepalese religious culture.

As part of this program, each participating Ward (an administrative unit within the city) formed an Animal Management Committee (AMC). AMC membership is decided by the Ward chairperson, an elected government position. Each AMC is supported by community volunteers, or Animal Management Assistants (AMAs), who are recruited by the AMC. They are local, respected individuals with a track record of caring for animals in their community, and they form the backbone of the dog population management intervention.

When Manu Mitra conducted a baseline survey, it found that roaming dogs—the targets of the intervention—were either unconfined owned animals or "community" dogs fed by one or more households or shopkeepers. The dogs were found to have positive cultural and religious significance to these communities, and the fact that the majority of dogs had an owner or guardian (and sometimes more than one guardian) necessitated obtaining permission for the dogs to undergo sterilization surgery.

This process required identifying the owner(s) or guardian(s) for dogs that roam before they were picked up for neutering and obtaining permission for the procedure. AMAs walked every street to identify roaming dogs and spoke to residents in order to identify owners and guardians. They also used public forums and focus groups to introduce the benefits of neutering and vaccination.

AMAs have multiple responsibilities related to the care of dogs, monitoring the streets for any new roaming dogs, and engagement of owners/guardians pre- and post-intervention, but specific to the permission process, AMAs are responsible for ensuring that dialog is both culturally appropriate and documented. Permission from at least one owner or guardian is required in order to neuter a dog. AMAs also assist in seeking permission for the veterinary team to humanely euthanize dogs who are suffering from poor welfare or illness, facilitating and aiding discussions with owners and guardians to avoid conflicts over euthanasia.

Also of note, when an owner or guardian cannot be identified for a dog, the AMA has authority to give permission for that animal to undergo neutering—a privilege that stems from their track record of caring for community animals and position of respect within the community. This permission, too, is documented.

In its three years of existence, Manu Mitra has achieved impressive results, and it has done so quickly: high rabies vaccination coverage, a stabilizing dog population, improved health among roaming dogs, positive changes in peoples' behavior toward dogs, and reported increases in residents' comfort walking around their communities. These successes can be credited to the extraordinary work of the AMCs and AMAs, including their respect for the rights and interests of dog owners and guardians within the community.

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BACK

ANIMALS TOOLKIT

INTRODUCTION

Animals as stakeholders

This toolkit is designed to provide guidance on how to evaluate and weigh the benefits and risks to animals in field projects, with particular attention to the ethical implications of the work being conducted.

Field projects can successfully and dramatically reduce the suffering and improve the health and welfare of animals. The capacity of projects to have this outcome should not be underestimated. Even with the best intentions, however, the path to achieving this goal may contain unforeseen obstacles and unintended consequences that can place animals at risk of harm (i.e., cause fear, pain, distress, or suffering).

Many of the standard procedures involved in projects, including capture, handling, restraint, caging or kennelling, vaccination, anesthesia, surgery, and release have the potential to harm animals and compromise their welfare. This is particularly true in field situations where outcomes are less predictable, access to animal care expertise may be limited, and project staff may have relatively little control over what happens when the animal is not under their immediate supervision. In addition to risks to target animals, there may also be indirect risks to other animals, such as livestock, wildlife, and non-target dogs and cats that are affected through their associations with the primary targets of the projects. All of these potential stakeholders need to be considered.

A note on the "3Rs" for animal research

For decades, the "3Rs" principles (Replacement, Reduction, and Refinement) have underpinned international regulations controlling the use of animals in research, especially laboratory research, and we therefore want to acknowledge them in this resource. They recognize that conducting research can cause animals pain, suffering, distress, or lasting harm, whether directly due to experimental procedures or indirectly due to breeding, housing, husbandry, or other factors.

The 3Rs are a framework to guide researchers in reducing harms to animals. Those planning to use animals in a study are expected to show why they cannot use alternative methods that do not involve living animals (Replacement), and what they will do to minimize both numbers of animals in the study (Reduction) and the suffering those animals experience (Refinement).

In the same way that traditional ethical review processes for human and animal studies don't fully apply to the context of field projects with dogs and cats, neither do the 3Rs. The projects that are the focus of this document are by necessity conducted on or with the target species, whether the objective is to directly benefit the lives of the participating individuals, or to benefit future generations of cats or dogs. Therefore Replacement is not a fully applicable principle. Reduction may or may not be relevant, depending on the risk of adverse effects; if a project is yielding overwhelmingly positive benefits, it could be desirable to increase the number of participating animals. Refinement is likely applicable, as there are nearly always being ways to improve a project, including but not limited to animal well-being.

Given these limitations we feel a more holistic and integrated approach is needed to ensure that projects are ethical from the standpoints of animals as well as other stakeholders.

What is "animal welfare"?

Before turning to ethical considerations and actions that a person or organization might take, it is worth focusing briefly on the core concept of "animal welfare." The term "welfare" broadly refers to the state of an individual. Different experts tend to emphasize different aspects of an animal's state when assessing its welfare (Fraser, 2008). Some prioritize unpleasant or pleasant subjective feelings and emotions (Dawkins, 1980; Duncan, 1993; Boissy et al., 2007); others focus on the animal's ability or inability to express "natural" or species-typical behavior (Rollin, 1995); and still others emphasize an animal's capacity to adapt to, and cope with, the demands of its environment (Broom, 1986; Broom & Fraser, 2007).

Regardless of these different views, animal welfare scientists generally agree that there is no single measure of an animal's welfare (Mason & Mendl, 1993; Appleby, 1999). Hence, they tend to advocate taking multiple measurements of things that are likely to be relevant, while at the same time recognizing that the final determination of an animal's welfare inevitably involves a degree of subjectivity (Dawkins, 1980; Mason & Mendl, 1993; Fraser, 1995).

Various animal welfare frameworks have been developed to assist in identifying and compartmentalizing the key components of animal welfare. These are summarized in chronological order, from left to right, in **Table 1**, beginning with the so-called Five Freedoms, the oldest and best-known framework. It was formalized in the late 1970s and has been further developed into a series of twelve welfare quality principles and, more recently, into five provisions or "domains" that emphasize the importance not only of minimizing negative welfare states but also promoting positive experiences.

All of these frameworks were developed primarily as guides to the welfare of animals housed under captive conditions, and their application to field projects have some limitations. For example, while project staff have a responsibility to provide fresh water and good nutrition to animals in their care, that responsibility may diminish once those animals are released back into their original environment. Nonetheless, at the moment, these frameworks are among the best resources available, and they can serve as a rough guide for field projects.

THE IMPORTANCE OF ANIMALS TO AN ETHICAL PROJECT

Since there are inherent risks of harm to animals associated with any project, we have an ethical obligation to do our best to identify those risks ahead of time and to take steps to avoid or reduce them whenever possible. When we cannot eliminate the risks to the animals entirely, we should carefully weigh the likely harms against the potential benefits to determine whether the balance between the two justifies our proposed actions.

In addition to attempting to predict harms and benefits to animals before they happen, those implementing a project have an ethical responsibility to ensure that the immediate and long-term impact of projects are properly monitored over time. Pressure to bring immediate relief to suffering animals, especially during times of crisis, may sometimes override questions concerning the long-term effectiveness of particular interventions.

However, if the aim is to produce significant and sustained improvements in the welfare of

Table 1: Animal Welfare Frameworks that Guide Animal Welfare Assessment

Five Freedoms (Farm Animal Welfare Council, 2009)	Welfare Quality Principles (Jones and Manteca, ND)	Five Domains Model for Animal Welfare Assessment (Mellor, 2016)
1. Freedom from hunger and thirst (and malnutrition) by ready access to water and a diet to maintain health and vigor.	1. Animals should not suffer from prolonged hunger, i.e., they should have a sufficient and appropriate diet. 2. Animals should not suffer from prolonged thirst, i.e., they should have a sufficient and accessible water supply.	1. Good nutrition: access to fresh water and a diet to maintain health and vigor. Minimize thirst; enable eating to be a pleasurable experience.
2. Freedom from discomfort by providing an appropriate environment, including shelter and an appropriate resting area.	3. Animals should have comfort around resting. 4. Animals should have thermal comfort, i.e., they should neither be too hot nor too cold. 5. Animals should have enough space to be able to move around freely.	2. Good environment: access to shelter, shade, suitable housing, good air quality, and comfortable rest areas. Minimize discomfort, promote thermal, physical, and other comforts.
3. Freedom from pain, injury, and disease by prevention or rapid diagnosis and treatment.	6. Animals should be free of physical injuries. 7. Animals should be free of disease, i.e., maintain high standards of hygiene and care. 8. Animals should not suffer pain induced by inappropriate management, handling, killing, or surgical procedures (e.g., sterilization).	3. Good health: prevention and rapid diagnosis and treatment of disease or injury, fostering good biological functioning. Minimize aversive experiences such as pain and nausea; promote physical activity, vigor, and strength.
4. Freedom to express normal behavior by providing sufficient space, proper facilities, and appropriate company of the animal's own kind.	9. Animals should be able to express normal, non-harmful, social behaviors (e.g., grooming). 10. Animals should be able to express other normal behaviors, i.e., it should be possible to express species-specific natural behaviors such as hunting.	4. Appropriate behavior: access to sufficient space, proper facilities, compatible company, and appropriately varied conditions. Minimize threats and unpleasant restrictions on behavior; promote engagement in rewarding activities.
5. Freedom from fear and distress by ensuring conditions and treatment which avoid mental suffering.	11. Animals should be handled well in all situations, i.e., handlers should promote good human-animal relationships. 12. Negative emotions such as fear, distress, frustration, or apathy should be avoided, whereas positive emotions such as security or contentment should be promoted.	5. Good feeling (positive mental experiences): access to safe, species-appropriate opportunities to engage in pleasurable activities and experiences. Promote comfort, pleasure, interest, confidence, and a sense of control.

animals, it is incumbent on us to employ the kinds of evidence-based approaches that are increasingly applied in other "crisis" disciplines, such as clinical medicine and wildlife conservation (Rosenberg & Donald, 1995; Sackett et al., 1996; Pullin & Knight, 2001; Sutherland et al., 2004; Ferraro & Pattanayak, 2006).

Such approaches place strong emphasis on the experimental deployment of projects, and the careful assessment of outcomes, to determine which practices are beneficial in the long-term and which are not.

ACTIONS TO TAKE AS PART OF A PROJECT

Measuring animal welfare

Methods of welfare measurement under field conditions should be feasible (practicable), valid (reflect true changes in animal well-being), reliable (give consistent results when used by different individuals at different times), and uncomplicated (not require specialized equipment, facilities, or extensive professional training to record and analyze). Welfare indicators should also be species-, life stage-, and project-specific.

Examples of direct animal welfare indicators that fit these criteria and which are likely to prove most effective in field contexts include:

- Body condition scores (e.g., standardized subjective ratings of an animal's overall body condition based on predefined categories ranging from emaciated to obese).
- Skin condition scores (e.g., standardized subjective ratings of the quality and condition of an animal's skin and fur).
- Presence of lesions (e.g., size, severity, and location of any lesions on the animal's body due to injury or disease).
- Other readily observable indicators of poor health (e.g., ocular or nasal discharge, diarrhea, labored breathing/respiratory distress, abnormal posture or gait, swellings or tumors, or ectoparasites).
- Behavioral indicators of pain, discomfort, fear, or distress (e.g., distress vocalization, inappetence, excessive panting, lethargy, excessive or lack of grooming/scratching, fearful/avoidant behavior, or negative/defensive social interactions).
- Behavioral indicators of positive welfare (e.g., normal self- and social grooming, play, exploratory behavior, or foraging/feeding).

Indirect indicators of animal welfare include:

- Animal population density and age structure (high-density and top-heavy age structure generally indicates intense competition for resources and high juvenile morbidity and mortality).
- Numbers of pregnant and lactating females (a proxy measure of reproductive activity).
- Human-animal interactions: the balance of positive (affiliative) and negative

(aversive) interactions between people and target animals in the community.

- Surveys of people's perceptions of, and attitudes toward, target animals, where negative attitudes tend to be associated with neglectful/abusive treatment of animals, and vice versa for positive attitudes.

See International Companion Animal Management Coalition (2015) for further details.

Planning for animal welfare assessment in project protocols

Protocols should clearly identify the process for assessment, the persons responsible for assessment, welfare indicators to be recorded (see above), the pathway to evaluate welfare, and steps required to enable remedial action to address welfare issues that result from the project (Nuffield Council on Bioethics, 2005). In some cases, the welfare state of individual animals in the field may be so poor that they are vulnerable to potential cumulative mental and physical suffering caused by standard practices inherent to the project (e.g., capture, transport, handling, restraint, or surgery). Due regard must therefore be paid to whether these animals should be included in the project, or whether euthanasia is more appropriate.

Subjecting animal welfare protocols to ethical review

Ensuring effective protocols to measure animal welfare throughout the project is a required part of any ethical review process. Whether the ethical review is conducted internally or by an external ethical review body, the same fundamental questions should be addressed in the protocol. Specifically:

- Has a thorough literature and background review been conducted to determine prior learnings about the safety, efficacy, and welfare impact of all proposed activities and procedures involving animals?
- What indicators of welfare will be measured (see above), and how were they determined or developed? When and how often will welfare indicators be recorded in relation to different events (or stages) in the project? What is the justification for this schedule?
- Who will record the welfare indicators (and what is their level of knowledge, experience, skills, and training), and how will the information be recorded and analyzed?
- What is the target population of animals, and the scientific and/or practical justification for the number and type of animals targeted?
- What precisely will happen to the animals throughout the entire course of the project or program?
    - Will the animals be subjected to capture or restraint? What methods will be used, and what is the potential for harm (fear, pain, suffering, or distress) to the animals using these methods? How will any likelihood of harm be mitigated?
    - Will the animals be housed or confined for significant periods? How will the animals be confined (e.g., crates, kennels, solitary or group housing), and for how long?

What are the risks of harm to the animals from this confinement method? What steps will be taken to mitigate these harms?

- What procedures (surgical, medical, etc.) will be performed on the animals? What are the potential harms associated with these procedures, and how will they be mitigated?
- Will the animals be marked for subsequent recognition purposes? What marking methods will be used, and what are the risks of harm to the animals from these methods? How will these risks be mitigated?
- What will happen to the animals at the end of the project? Will they be released, rehomed, or euthanized? What are the risks of harm associated with these endpoints, and how will they be mitigated?
- If euthanasia is the endpoint, what justifying criteria will be used, and how will they be determined?

- If a serious adverse event (e.g., something with a severely painful or distressing impact on welfare) occurs during the course of the project, what remedial actions will be taken, and by whom?

(*Adapted from Hawkins et al 2011.*)

CHALLENGES IN THE FIELD

Organizations and individuals undertaking field-based projects face numerous practical restrictions, constraints, and challenges when it comes to predicting potential sources and levels of harm to animals. Because field conditions may limit our abilities to take swift remedial action, even mild or moderate harms to animals can quickly escalate to severe, thereby causing the animal unnecessary suffering. It is therefore important to define selection criteria for animals to be part of the project, and to consider their current welfare state and whether they will be able to cope with the additional welfare insults that may result from their inclusion. The unique contexts and circumstances under which the project will be conducted in the field also has bearing on our ability to evaluate animal welfare and refine practices in light of the predicted harms. These suites of interacting factors should be considered and should inform a harm-benefit analysis and be identified during the ethical review process. Including local partners and individuals with the necessary field experience in discussions (see the **Communities Toolkit**) will help to identify specific challenges likely to influence animal welfare in the field.

Challenges in the field that may impact animal welfare

Specific challenges that may have an impact on animal welfare include:

- Depending upon country or region, trained veterinarians and animal care staff may not be locally available in the field. Veterinarians and associated animal care staff (e.g., paravets, animal welfare officers, veterinary technicians, assistants, and nurses) play a critical role in protecting and enhancing animal welfare through their knowledge of

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animal health, their ability to handle animals safely and humanely, their understanding of pain management and humane endpoints, and their experience of euthanasia.

- Animal care capacity may be reduced in the field. The veterinary and animal care capacity in the field should ideally match the specific animal welfare requirements of the study (e.g., the predicted nature and severity of the harms it may cause). In particular, animal care personnel should possess:
    - Appropriate professional and technical competency, knowledge, skills, and abilities in veterinary and animal care, including direct experience of working with dogs and cats (in some countries vets are trained predominantly to work with livestock and may have little, if any, direct clinical experience with dogs or cats). It may be necessary to specifically identify their understanding of:
        - Canine/feline husbandry and care
        - Canine/feline behavior and welfare
        - Canine/feline health, clinical signs of disease, pain, depth of anesthesia, etc.
    - Local veterinary and animal care staff may hold different values, attitudes, beliefs, and ethics surrounding animals, their treatment, and euthanasia. These differences should be identified and discussed in advance, and consensus should be reached

CASE STUDY

A comprehensive dog handling program improves animal welfare and creates positive community change

An organization that operates large-scale catch-neuter-vaccinate-release (CNVR) programs in Asia developed a comprehensive humane dog handling program. The program's objective is to improve the welfare of dogs and promote a change in behavior of people towards community and free-roaming animals.

The program is committed to treating dogs with care and compassion, and to ensuring that no unnecessary force is used during capture, with restraint, or at any other time during the intervention. This is important for dog welfare, and it is also important to foster a positive view of dogs in the community, since the care that they receive from the organization while being caught, transported, and returned to their community is fully visible to residents.

Before developing the new program, the organization identified all points of human contact with dogs, from pre-capture to postoperative checks on the street following surgery. The resulting process began with a comprehensive training program in animal behavior and welfare for project staff, including the Animal Welfare Officers (AWOs) who have the most extensive interaction with dogs: they catch and handle them for treatment, care for them at the spay/neuter clinic, and monitor them after release.

Note the choice of title. Project staff (previously dog catchers, paravets, and cleaners) were renamed Animal Welfare Officers because all are required to handle and interact with dogs in their roles. Making them AWOs made them responsible for the dogs' welfare as their priority, regardless of the task they were doing.

AWOs tailor their strategies for catching dogs to the individual community. AWOs begin with hand-catching techniques only, using treats to encourage dogs to approach them and then picking them up. Once they reach all the socialized and "hand-catchable" dogs, the team catches the more fearful dogs with nets.

Although there are variations by community (when people generally do not treat dogs very well, dogs are mostly scared), the team observed that in communities with no prior dog-catching activities, often 60 percent or more of the dogs were catchable by hand. In communities where dogs had previous exposure to dogcatchers who used tongs, loops, and nets, 30 percent or fewer of the dogs were hand-catchable.

Once dogs are caught, the AWOs continue to provide gentle and sympathetic support while transporting them for sterilization surgery. At the clinic the dogs are regularly and positively interacted with throughout the whole process, facilitating effective welfare assessments that prompted changes in the anesthetic and analgesic protocols to improve animal welfare.

The community observes dogs being treated with kindness, in contrast to other dog catching methods that appear cruel (e.g., using tongs). Over time, community members have been found to provide better care to dogs following the CNVR intervention, during which they observed dogs responding positively to kind and sympathetic handling. This said, as with any region, individual communities vary in attitudes and behavior.

For this organization, positive change was most evident in poorer communities. Initial dog density was higher in these areas, people were more tolerant of dogs, and the organization saw real, positive change after the intervention. When team members evaluated impact 3–6 months after the initial intervention, they found that more people would bring dogs for sterilization (indicating an increase in dog ownership).

Residents reported that they were happy that no more puppies were being born (some even had to go to other villages to get a puppy). In one area, by the second year of the project, it had become fashionable to adopt a street dog!

This simple but holistic approach to animal welfare improvement has been replicated with other CNVR programs around the world.

on protocols surrounding animal care and euthanasia to minimize the chance of conflicts when the project is underway.

- Lack of appropriate housing: If animals are to be held for a research study, there may be environmental or physical conditions that make it difficult to house animals comfortably, whether singly or with compatible animals of the same species, and/or for varying lengths of time. Minimum standards of housing may fall below those recommended in the Five Freedoms.

- Availability of veterinary drugs: Veterinary drugs that are important to help alleviate animal suffering in the field (e.g., anesthetics, analgesics, euthanasia, and antibiotic agents) may not be available, or their local supply may be unreliable due to:
    - Restrictions in local licensing and supply chains, including the import of controlled veterinary drugs.
    - Local regulations with strict requirements for the storage of controlled veterinary drugs, which cannot feasibly be met in the field.
    - Local regulations concerning the use of controlled veterinary drugs by trained operators or suitably qualified personnel (e.g., the administration of barbiturates or opioids to animals by qualified veterinarian). N.b.: If there is no recognized suitably qualified person present locally, you may not be able to obtain controlled veterinary drugs to enable safe and effective anesthesia to alleviate pain or perform humane euthanasia.

Addressing challenges in the field

It is incumbent on organizations to identify specific challenges in the field that may arise from the unique and varying contexts or circumstances under which the project is being conducted, and which may have an impact on animal welfare. Depending upon the nature of the specific challenges, these may be addressed through:

- Building local capacity via training and mentoring to ensure competency of key personnel.
- Building capacity in animal welfare and ethical decision-making using participatory approaches so that all field staff are involved in planning for and designing the project, as well as preparing the project for ethical review (if appropriate).
- Supplying veterinary and/or animal care capacity to the field site by employing outside personnel with desired skills and competencies (n.b.: there may regulatory or licensing restrictions that prevent you from doing this; this may also create tensions with local veterinary or animal care personnel).
- Building in monitoring approaches to ensure that agreed-upon standard operating procedures and project protocols are being adhered to.

- Building steps or approaches into project plans that help to address the specific challenges also requires careful consideration of what happens at the field site or location after you leave. The aim should be to ensure that any positive welfare changes are sustainable upon exit, and that owners and/or communities do not become dependent upon primary veterinary services that cannot be sustained long-term.

Definitions and descriptions of terminology related to animal welfare are provided in Appendix 1: **Glossary of Animal Welfare Terminology** at the end of this toolkit.

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APPENDIX 1

Glossary of Animal Welfare Terminology

Adverse event/effect (Lewis et al., 2002)

A serious physical change that is induced in the animal that adversely affects the animal's well-being or general condition, growth, development, or life span. It may be difficult to predict adverse events or effects during a project.

For example, adverse events may result from the animal's reaction to drugs administered in the field (particularly where veterinary drugs may be substituted or combined or replaced by human medicines due to poor local supply, and their actions or effects on animals are poorly understood). See humane endpoints (below).

Animal welfare

Animal welfare refers to an animal's state and ranges from good to poor. Animals experience both positive and negative welfare states.

Different definitions of animal welfare have emphasized such measures as how the animal feels; whether the animal is able to express natural or species-typical behavior; and how well the animal is coping with, or adapting to, the circumstances of its current environment. All of these factors contribute to an animal's welfare.

Animal welfare assessment

Animal welfare assessment refers to the ways in which we measure and evaluate animal welfare. Assessments may include measures of the animal's environment, husbandry, and care provided by humans (known as resource or input-based), and animal-based indicators of welfare. Animal-based measures of welfare include behavior, physical health, and physiological indicators recorded from the animal.

Contingent harm

Harms inflicted indirectly on other, non-target animals or persons as a consequence of their associations with the target animals.

Cumulative severity/suffering (RSPCA, 2019)

Suffering as a result of the overall effects of the things that are "done" to animals, where the animal experiences events repeatedly or in combination to increase the overall severity of the experience. Animals in a poor welfare state who are included in a project may experience cumulative suffering, resulting in severely compromised welfare or even death.

Direct harm

Pain, fear, suffering, or distress resulting directly from the things done to the target animals as part of the project.

Distress (Janczak, 2010)

Experience of severe pain, fear, or anxiety.

Euthanasia (WSPA, 2007)

A good death; euthanasia refers to an act that brings about the premature death of an animal and, if properly carried out, should not cause the animal pain, suffering, or distress. The feasibility of using suitable methods for humane killing in the field should be identified in advance to ensure compliance with the four criteria for euthanasia (see WSPA, 2007).

The decision-making process surrounding euthanasia for organizations working in the field, and how they can be addressed in advance to help establish policies and protocols, are described in more detail in ICAM (2011).

Fear (Janczak, 2010)

An aversive emotional reaction induced by perception of stimuli associated with danger, which leads to protective defense reactions.

Humane endpoints (Utrecht Life Sciences, 2016)

In animal research, humane endpoints describe the identification of clear, predictable, and irreversible criteria that can be substituted for more severe outcomes such as intense suffering or death. They should be considered whenever a project could result in acute or prolonged suffering or death to a target animal.

Developing criteria for humane endpoints is not easy, particularly in field contexts. Humane endpoints should be agreed upon at the project planning stage, and the decision-making processes regarding when to employ euthanasia should be identified in advance. These decisions should include considerations of the owner, and the criteria for humane endpoints should be discussed as part of the informed consent/permission process.

Pain (Janczak, 2010)

An unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain can be alleviated by the provision of appropriate and suitable analgesia.

Pain, fear, suffering, distress, and lasting harm (Animals (Scientific Procedures) Act 1986)

These are key terms used to consider harms to animals when they are used in research. The terms are typically associated with situations in which an animal experiences disturbance to normal health (physical, mental, and social well-being), including disease, injury, or physiological or psychological discomfort.

These disturbances could be immediate or longer term as a result of things that are "done" to the animal, or through deliberate acts of omission, such as not doing something that protects its welfare (e.g., failure to provide food or water).

Severity banding/classification (European Commission, 2009; RSPCA, 2019)

Refers to an approach that describes the likely levels of suffering (e.g., mild, moderate, severe) that an animal may experience when used in research. It is commonly used during ethical review and informs the weighting of harms against benefits.

- *Mild:* Experience of short-term mild pain, suffering, or distress. The animals are not likely to experience significant impairments to their well-being or general condition. Examples include handling and brief humane restraint to give an injection or take a blood sample.

- *Moderate:* Experience of short-term moderate pain, suffering, or distress or long-term mild pain, suffering, or distress, resulting in moderate impairment to well-being or general condition. An example is surgery under suitable, appropriate, and effective general anesthesia and analgesia.

- *Severe:* Experience of severe pain, suffering, distress, or lasting harm, resulting in severe impairment to well-being or general condition. Examples include surgery without sufficient and appropriate anesthesia or analgesia, or experiencing certain adverse events.

Suffering (Nuffield Council on Bioethics, 2005)

A negative emotional state that results from adverse physical, physiological, and psychological circumstances, in accordance with the cognitive capacity of the species and of the individual being, and its life experience.

Unnecessary suffering (Hurnik & Lehman, 1982)

Suffering is considered unnecessary when it is not essential for purposes of sufficient importance, or if it could be avoided by adopting alternative practices that would achieve the same purpose but would result in less animal suffering.


BACK

OWNER, GUARDIANS & CARETAKERS TOOLKIT

INTRODUCTION

Relationships between humans and animals vary widely, and these variations can be particularly evident in field contexts.[1] Many dogs or cats are cared for by a single person or household, but under certain situations more than one person or household claims interest in the animal. Alternatively, individuals might provide some care to cats or dogs because they are concerned about their welfare, but they do not identify as the owner or guardian. It is also possible for cats and dogs to be "unowned," living amongst communities and accessing human-mediated resources for food and shelter.

It is certainly possible to observe this broad spectrum of ownership in a single study. If this happens, it can be challenging to identify the individual(s) who claims some right over an animal, and to navigate engagement with both humans and animals in an appropriate manner.

Working with animals in a field context can make for both logistically and ethically-challenging situations.

For example:

- How do you work with individuals who want their animal to take part in a research or non-research-based project for seemingly "wrong" reasons?
- What do you do if an owner or guardian is not acting in the best interest of an animal—e.g., is against euthanizing a dog or cat who is suffering?
- And do you need consent from all individuals who exert "loose" ownership of an animal to enroll that animal in a study?

These are but a few of the questions that might arise when conducting a field study. While there is no single "right" or "wrong" answer to these questions, having a solid understanding of and respect for the owners/guardians with whom you are working is essential to navigating the "human" element of field studies in a thoughtful and ethical manner.

1 The ICAM Coalition's *Humane Dog Population Management Guidance* and *Humane Cat Population Management Guidance* publications provide excellent discussion of different types of dog and cat "ownership" and ways in which these species live in communities.


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Even so, identifying, understanding, and respecting the variable and complex relationships between animals and humans in a community, and the local norms for human-animal relationships, is an essential aspect of conducting a study. No matter what the relationship, owners and guardians are important stakeholders, and they can be positively or negatively impacted by the design and conduct of the study. The risks, burdens, and benefits to individuals should take into account the nature of their relationship with the animals who are candidates to participate in the study. They should then be informed of the benefits and the risks using appropriate language for individual circumstances, including education level, familiarity with the study, and relationship with the animal. Above all, it is crucial that human stakeholders provide informed permission regarding inclusion of their animal in a study (see **Consent and Permission Toolkit**).

Exploring the types of ownership and guardianship in a particular community will aid in adopting an appropriate approach for conducting a study in an ethical as well as legal manner, and in identifying how to best engage animal owners and guardians. This effort is an integral part of planning and preparing to conduct a study.

What's in a name?

A variety of terms are used to describe the person responsible for a dog or cat: "owner," "guardian," and "caretaker," among others. Different terms have different legal, social, and ethical implications, and thus warrant consideration when conducting studies involving animals.

The term "owner" denotes the person in charge of an animal, but it also conveys possession. There are inherent issues with "ownership" terminology, however, beginning

with the fact that animals are not things. Cat and dog sentience is widely accepted in scientific literature, and even in legal regulations in many countries. Possessing consciousness means that animals care what happens to them and have preferences and interests, which warrants reconsidering and updating terminology.

Guardianship relates to the position and responsibilities of a guardian, especially toward a ward, involving concepts such as care, responsibility, and charge. Guardianship is the term used for the caring of individuals who are not completely autonomous to take full responsibility for their own well-being.

Guardian seems a more appropriate term in relation to animals considering modern scientific knowledge and the context of animal protection. We therefore in concept prefer the term "guardian" to "owner," though we recognize that regulations, legal considerations, and social convention most often entail use of "ownership" terminology.

Regardless of the terminology you use, we encourage consideration of the implications of the choice of term.

RELEVANCE FOR AN ETHICAL INTERVENTION

Dogs and cats are distinct from other animal species in their relationships to humans and diversity in the roles that they occupy in human society (Turner & Bateson, 2000; Bradshaw et al., 2012; Serpell, 2017). They may inspire strong emotional attachments from people, have religious or cultural significance, be feared, be considered "pariahs" (unclean or untouchable), or be perceived as harmful to people (Turner & Bateson, 2000; Bradshaw et al., 2012; Serpell, 2017). They can positively impact their owners/guardians by providing companionship and emotional support, offering protection, or contributing to human livelihoods through, e.g., herding or guarding livestock, or controlling pests. Owners/guardians can also be negatively impacted by dogs or cats for a variety of reasons: threats of zoonoses (rabies, parasites, or bacterial infections); burden of decisions around or cost of veterinary treatment, including euthanasia (Christiansen et al., 2016; Belshaw, 2017); when the animal is no longer able to "work"; or when the animal's behavior causes problems for the owner, family, or community (Podberscek, 2006).

The complex relationships that dogs and cats have with humans mean that field studies targeting these species can impact owners positively and negatively—and potentially both at the same time!

Roles of owners, guardians, and caretakers

Just as dogs and cats occupy diverse roles in relation to people, people engage with and care for these species in diverse ways.

At one end of the spectrum is an "owner" in the eyes of society and/or law. Where owners are legally recognized, evidence of ownership may be conveyed through animal identification (e.g., a microchip, a collar and tag), documents listing a person as the owner, or records at a veterinary clinic. When animals are classed as property, it can give the

A note on dogs versus cats

Just as we cannot assume that "one size fits all" when it comes to the relationships between humans and animals in a community, we cannot assume that cats and dogs receive the same legal treatment, or are cared for in the same way by owners or guardians.

Regulations may state separate legal obligations for guardians. For example, in the United Kingdom and United States cats have the legal right to roam, whereas dogs do not. Thus, guardians are obliged to control and supervise their dogs in public places, but not their cats. In many countries, however, guardians are not required to supervise their dogs.

owner legal rights, protections, and recourse. This has implications for conducting a study insofar as there might be legal requirements to obtain permission to do something to an animal as part of a study, regardless of whether it is for the benefit of the animal.

It is important to remember that "owned" animals may or may not roam freely, and the care they receive may or may not be viewed as "responsible" or "good." It is similarly important to recognize that the concept and definition of "ownership" varies (ICAM, 2007; 2011). In some locations and cultures, "ownership" might not match the above description. There might not be legal recognition of an owner or an owned animal, or animals might occupy different roles within the society that influence how humans view animals and responsibilities toward them. In some contexts, the term "owner" might also be applied to anyone who claims some right over an animal, regardless of whether they care consistently or responsibly[1] for them. This could include, for example, a person who intermittently feeds free-roaming animals (ICAM 2007; ICAM, 2011).

In some circumstances, a person will provide care for or claim over a free-roaming animal without identifying as the "owner." In such a situation, individuals may identify as "guardians" or "caretakers," and the animal may have the status of a "community" dog or cat.[2] In some cases, more than one person will claim some form of interest or concern for an animal, meaning that dogs or cats may have a group of people sharing in their care. This can benefit both individual animals and broader communities; if the free-roaming animals have been sterilized and vaccinated, they can potentially help turn free-roaming animals

1 Note that individuals might be prevented from providing consistent care to animals due to economic or societal constraints, rather than a deliberate act of omission. In other words, they are doing the best they can given their circumstances, and this should be respected.

2 The term semi-ownership has been used by some authors to broadly describe individuals that interact with or provide some care for animals but may not directly admit ownership of them (Toukhsati et al., 2007).

from potential public health hazards to reproductive and sanitary barriers (Molento, 2014).

There may also be instances where there is no clear caretaker or guardian for an animal. Cats and dogs may be unowned, living amongst communities, accessing human-mediated resources for food and shelter. In this scenario, some countries legally define animals not under the responsibility of a specific person or group of people as belonging to the government or State and a diffuse and collective interest of the people.

It is worth noting that the relationship between an animal and human(s), as well as the extent to which an animal is confined or roaming, does not in itself dictate the animal's quality of care received or quality of life. The International Fund for Animal Welfare (ifaw) developed the term "adequate guardianship," which describes the minimum care needed for a dog or cat in order for the animal to maintain an acceptable level of welfare.

Implications for conducting a study

The varied and complex relationships between humans, dogs, and cats, as well as the local norms for human-animal relationships, might affect peoples' feelings about a study. This will affect the risks, benefits, and burdens of the study, and influence whether people are positively or negatively affected.

There may be differences in how people engage with and care for dogs and cats, and it is certainly possible for a community to have a combination of owned, community, and unowned animals—and people who identify accordingly. There may also be situations in which multiple people will claim a particular animal, yet differ in their choices for treatment of that animal. In short, human-animal relationships are not "one size fits all," and it is essential for the study to adapt to this reality.

Our legal responsibilities are most clear with regard to people who are classed as legal owners of animals included in a study. However, it is essential that we don't neglect our ethical responsibilities toward any groups, particularly those who have more complex or nuanced relationships with dogs or cats in the community.

PRACTICAL ACTIONS TO TAKE

Become familiar with laws, regulations, and codes of practice

Although this is not solely an ethical consideration, it is essential that those seeking to conduct a study are familiar with local laws and regulations, including but not limited to animal ownership and permission to enroll an animal in the study, and ensure that study protocols are in accordance with them.

Identify and become familiar with local norms

It is important to understand the local norms and practices around animal ownership, guardianship, and/or caretaking. Keep in mind, as well, that in some communities dogs or cats are abundant and tolerated but rarely provided with consistent or deliberate care. At

the same time, these communities have an interest in the animals and what they perceive as their welfare, and they would not accept actions that they perceive to interfere with those animals (Serpell 2017). They would not accept the animals' removal and might object to a project, including one that seeks to enhance animal welfare.

Identify owners, guardians, and caretakers

The process for establishing the person(s) to grant **permission** for an animal to take part in a project may not be straightforward and could require detailed discussion and planning at a local level. Keep in mind the following:

- Animals might be free-roaming. The term "roaming" refers to a behavioral state and can span all categories of ownership status: owned, semi-owned, lost, abandoned or unowned (ICAM, 2007; 2011). Consequently, the fact that

CASE STUDY

Developing a shared guardianship structure for community dogs

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Curitiba, a city in the South of Brazil, is home to approximately 1.9 million human residents and an estimated 475,000 dogs, a large number of which roam freely. Until 2005, free-roaming dogs were captured, held for three days in a municipal shelter, and if no one claimed them, they were eliminated. This was regular practice for many decades, though it was clear that dog population control would not be achieved through this process. After major protests from concerned citizens, the dog elimination policy was outlawed.

Today, the city maintains more intensive dog sterilization campaigns and has started a Community Dog Program. The program is one of shared dog guardianship. Dogs are identified, vaccinated, dewormed, surgically sterilized, and returned to their community by the municipality, which covers the cost of these procedures. Meanwhile, residents accept formal responsibility as a dog's caregiver and register as such with the Municipal Environmental Secretariat. They agree to feed the animal (something most people are already doing), provide shelter, and cover the cost of everyday items for the animals. They are also responsible for monitoring the dog's health and calling the municipality for veterinary care when needed. The municipality's disease control centre maintains periodic contact with all caregivers.

This is an example of shared guardianship involving citizens and the municipality, which tends to reward those who care for animals and foster respect for dogs. The work has brought an unexpected level of contact between animal control agents and the community, and improved relations between the two while also enhancing the well-being of dogs.

For more information, see: Molento, C.F.M. (2014). Public Health and Animal Welfare. In: M.C. Appleby, D.M. Weary, & P. Sandøe, *Dilemmas in Animal Welfare* (pp. 102–123). Wallingford, UK: CABI publishing.

an animal is roaming does not exempt a person from obtaining permission for the animal's participation a project.

- An individual dog or cat could have multiple guardians. Obtaining permission for that animal's participation might mean engaging more than one individual and identifying ways to address or mitigate disagreements between individuals.
- It may be challenging to identify informal guardians. They might provide care very discretely, particularly in contexts where those who feed "stray" animals are criticized or even punished.
- Even after extensive effort, it might not be possible to identify an owner or guardian. If there is a desire or benefit to include such animals in the study, a process for obtaining permission for participation in the study must be established. In one spay/neuter program, for example, when an owner or guardian could not be identified, a community volunteer had authority to give permission for that animal to undergo surgery. In other instances, local law may consider the State responsible for abandoned animals, including those without an identified guardian, in which case the State may hold the power to take final decisions regarding spaying/neutering the animals, as well as proceeding with any needed veterinary care.

Household questionnaires and participatory approaches can aid in identifying owners/guardians and others who provide some form of care or are invested in what happens to animals. These methods can explore peoples' knowledge, attitudes, caregiving practices, and beliefs about animals and topics (e.g., vaccination, sterilization) that could influence a study's success.[1] Similarly, questionnaire and participatory approaches can be adapted to explore beliefs around euthanasia, which may be undertaken during studies to alleviate the suffering of individual animals, and which often leads to conflict due to different ethical positions.

When using these methods to collect information or data from humans, follow the guidance and additional information provided in the following toolkits:

Data Collection and Use Toolkit

Informed Consent and Permission Toolkit

Communities Toolkit

1 Detailed methods on the use of questionnaires and participatory approaches for monitoring and evaluating dog population management interventions are available in the International Companion Animals Management Coalition document *Are we making a difference?* (2015). These tools are also very applicable to cats. For example, Toukhsati et al. (2007, 2012) used questionnaires with a Likert-type scale, administered via telephone, to identify semi-ownership practices of Thai nationals towards dogs and cats, including knowledge, beliefs, subjective norms, intentions, and attitudes. This approach helped to identify perceived barriers to sterilization and opportunities to engage communities in a relevant way by understanding social norms.

Evaluate risks, benefits, and burdens for people

The process of planning for a study should include identification of risks and benefits to the people who are directly or indirectly involved in the study (as well as the risks and benefits to the animals; further details on risk/benefit analysis are discussed in the Ethical Review Toolkit). To identify risks and benefits, it is essential to take into account the varied nature of peoples' relationships to animals, and not to underestimate the importance of animals to informal or irregular caretakers. These individuals might benefit from companionship or roles that animals occupy in society; there may also be perceived cultural or religious significance for providing care or demonstrating kindness to animals.

Engage (human) stakeholders in decision-making processes regarding inclusion of animals in the study

Owners/guardians are important stakeholders, and they may be strong collaborators to the design and conduct of the study, particularly since they can add valuable information to understand the dynamics of the dog or cat-human relationship in the specific community. If possible, they should be included in the study's planning stage.

As noted above, it is essential to gain permission from owners/guardians for an animal's engagement in a study. This process should involve a discussion and dialog that details the potential benefits and risks of the study using appropriate language for individual circumstances, including education level, familiarity with the study, and relationship with the animal.

Identify and preserve current animal care

Planning for a study should include identifying the type and level of care and attention that

people currently provide animals, and putting steps in place to guarantee that these are appreciated, preserved and, if possible, strengthened and broadened.

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COMMUNITIES TOOLKIT

BACKGROUND

What is a community?

Though difficult to define precisely, a community is most often a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings (MacQueen et al., 2001). Often, a community has a geographic boundary, though the term "community" may also relate to a specific group (with or without geographic boundaries), such as a religious, socioeconomic, professional, or values-based community. For the purposes of this document, we will use the term "community" to refer to a group of people living together in the same place.

No two communities are exactly alike. Any community is a set of unique and diverse stakeholders, each with their own set of practices, customs, and values. The interactions between these stakeholder groups are one of the variables that make each community unique. In addition, most communities have both formal and informal power structures which result from culture, economics, political structures and personality. As a result, it would be impossible to define a single way to interact with "communities." In light of this, the following guidelines are not a prescriptive formula, but a set of considerations that aim to help the user understand:

- Why communities are important stakeholders in community animal interventions.
- Diverse relationships communities may have with their community animals.
- How to design a project in collaborative, ethical partnership with a community.
- How to implement measures to maximize benefit and minimize harm of an intervention to communities.

Why are communities an important consideration in dog/cat interventions?

Communities that share living space with dogs and cats are important stakeholders in any intervention that may change the relationships they have, or the ecological balance, with the dogs and cats in their communities. Because dogs and cats often have individual relationships with members of the community and may form strong bonds with people, any intervention which impacts these animals will probably affect members of the community, in both positive and negative ways.


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All communities will already have some way of managing the dogs and cats in their community, whether the animals are owned or unowned. These methods may range from reactive (reacting only to consequences of dogs and cats, such culling abandoned animals) to active (attempting to intervene in the lives of dogs and cats to change the impacts they have on the community, such as sterilization or sheltering). Ideally, these management measures are undertaken by owners or guardians. In communities with free-roaming animal populations, management may be formally organized by the municipality or some group exerting authority, or it may be informal, in which members of the community take it upon themselves to intervene by, e.g., feeding or caring for sick animals, removing or killing animals, or restricting the movement of animals.

When an intervention conceived outside the community changes the way a community maintains its animals (owned or unowned), it represents a change in the status quo. Some community members are likely to be supportive of changes, others will feel ambivalent, while still others are likely to feel unhappy or threatened by change. Whatever category they fall into, community members will ultimately be responsible for accepting or rejecting the changes introduced by the project. Persistent negative messages promoted by detractors can undermine a project, no matter how well designed, and reduce participation, spread negative rumors, or even lead to vandalism or protest. Positive messages can generate support, energy, enthusiasm, and cooperation of community members, making target populations of animals easier to reach and interventions easier to implement and ultimately more sustainable.

Community members themselves are experts in local communication. While formal power and communication structures may be evident to the outsider, informal power and communication—which may hold more ultimate influence over the daily lives and interactions within communities—are more readily accessed by community members and insiders. It is therefore critical that any intervention initiated by outsiders build strong ties with community members, who can help in promoting positive messages and dispelling negative ones through the informal networks in the community.

Communities are also, ultimately, those that will derive benefit or shoulder the burden of risk when a project takes place. While an intervention may seek to improve the welfare of individual animals, it may impact many other factors in the communities, including: social interactions between community members; cultural practices regarding the role of animals in humans' lives; livelihoods and economic factors impacting owners, veterinarians, and others; health and safety of community members; burden on healthcare systems; interaction with and confidence in local governance; and the joy individuals derive from their environment (Atema & Arluke, 2015). It is therefore critical that any project assess a community's well-being from these angles and implement strategies to enhance potential positive outcomes and mitigate risks to a community's well-being as a result of the intervention.

Finally, it is important to note that many indigenous and rural poor communities where dog and cat interventions are targeted may be particularly vulnerable to changes promoted by outsiders. Power imbalances will be inherently present when an outsider proposes positive changes the community seeks. As such, it is important to ensure that project protocols, risk mitigation strategies, local communications strategies, shared impact reporting, and external communications protocols are set up in collaboration with community members in advance of project implementation. The topic of **informed consent and permission** is addressed in a separate toolkit, but is especially important with regard to vulnerable communities, where literacy and agency may not be uniform (Warrington and Crombie, 2017).

Relationships between communities and their animals

Communities may have varied relationships with their dogs and cats, some of which may not be obvious to the outsider. Around the world, people interact in different ways with their dogs and cats:

- Dogs and cats may roam freely during the day, interacting with the public, but return to caring homes at night.
- Dogs and cats may stay confined during the day but roam freely at night.
- Dogs and cats may stay confined for long periods out of concern for their safety.
- Roaming dogs and cats may be tolerated and be highly socialized.
- Roaming dogs and cats may be poorly tolerated and subjected to abuse, dangers, and/or inhumane management.
- Dogs and cats may be unowned or loosely owned, cared for by members of the public.
- Dogs and cats may be owned, but not well cared for and in a poor welfare state.
- Owners may take great pride in their animals but be unaware of how to meet their basic needs.
- Owners may be aware of their animals' needs but be unable to meet them because of lack of funds or lack of available care.
- And, of course, dogs and cats may be well cared-for in a community that has systems promoting their welfare and safety.

One of these conditions may predominate in a community, but in many cases, several of these conditions exist at once, complicating a community's response to potential interventions.

Community member attitudes and reactions to these conditions can also vary widely, even within a single community:

- Community members may be deeply concerned about the welfare of animals in their environment.
- Community members may feel the situation is acceptable and requires no action.
- Community members may feel their safety and well-being is seriously compromised due to risk of disease, dog bites, or nuisance in the environment (e.g., noise, spreading trash, feces).
- Vulnerable populations, such as children and the elderly, may be most at risk from animal bites or transmission of parasites due to their increased contact with the physical environment.
- The presence of cats and dogs may elicit strong feelings and opinions that can polarize individuals in communities, which may escalate into serious interpersonal conflict.
- Communities may be intolerant of euthanasia and believe that animals have a right to life over quality of life considerations.
- Communities may be inherently wary of innovations or interventions because of their previous experience with external organizations or other projects targeting dogs or cats which failed to resolve their concerns.

It is imperative that anyone planning an intervention understands these relationships, animal management styles, and desires for ideal human-animal interactions before proposing an intervention. Through good stakeholder engagement, these attitudes can be uncovered and meaningful projects can be designed to address a community's concerns.

ETHICAL PRINCIPLES FOR WORKING IN COMMUNITIES

Community partnership

The way in which we approach individuals and communities creates a relationship that can have a lasting impact. Community-based interventions should aim to establish a collaborative and beneficial relationship between the community and the external partner that reflects mutual respect and cooperation.

Long-standing ethical research principles of respect, beneficence, and justice from the field of human research (National Commission, 1979) can be applied to work with communities as well. These methods include: considering the short- and long-term impacts of the project on individuals and the community; ensuring that harm to the community is

minimized and benefits are maximized; and ensuring the equitable selection of subjects/participants from within the community's stakeholder groups, and the sharing of research outcomes with the community (CARE, 2009).

Key steps to achieve this, which are elaborated on in the step-by-step guidelines below, include:

- Agree on terms of partnership reflecting mutual respect and cooperation.
- Promote diversity by ensuring baseline research and involvement is broadly representative.
- Shared decision-making between outsiders and the community in the planning and risk mitigation strategies.
- Shared benefits and rewards from the findings or outcomes of the innovation or intervention, particularly where research is concerned and benefits to the community may be less obvious.
- Ensuring adequate monitoring, evaluation and communication of project outcomes.
- Promoting sustainability of positive outcomes through sustainability planning from the outset.
- Training members of the community in the design and conduct of the project and in upholding ethical principles.

The principle of participation

The United Nations (UN) Human rights-based approach to programming asserts that people have a right to be involved in informing decisions that will directly or indirectly affect them (United Nations, 1986; 2003). Ideally, a project is designed with the active participation of those who stand to benefit, although where research or novel interventions are being tested, this may not always be entirely possible. However, using a participatory approach to project conception, design (to the extent feasible), implementation, and monitoring strategies is desirable.

Using participatory approaches means involving stakeholders, particularly those affected by an intervention, in the process of discovering the need and making decisions about activities that could impact their lives. This includes involvement in the design, data collection, analysis, reporting, and management of the project (Guijt, 2014). The term "participation" covers a wide range of different types of participation, which differ in terms of whose participation is wanted, and what it is that those people are involved in and how. By asking the question, 'Who should be involved, why, and how?' for each step of a project (see **Stakeholder Engagement Toolkit**), an appropriate and context-specific participatory approach can be developed (Guijt, 2014).

Capacity required for effective community engagement

Because effective community projects require personal communication and engagement with communities, it is critical that any intervention has one or more locals on the team. These persons may be from the same community as the intervention, the same culture, or simply familiar with and accepted by locals. Before engaging with a community, it is critical to identify and secure staff, contractors, or partners with the necessary skills and experience. These include:

- Knowledge of and experience working in the environment targeted for the project.
- Knowledge of local cultural or political tensions.
- Local language fluency.
- Rapport building and facilitation skills (these need not be formal).
- Respect for animal welfare and ethical research.
- Flexibility and resourcefulness.

IDENTIFYING AND ENGAGING STAKEHOLDERS

Who or what is a stakeholder? A stakeholder is any person, group, or organization that can affect or be affected by our actions, plans, objectives, and policies; literally anyone who has something "at stake." For the purposes of this guide, a stakeholder is any person or organization that needs to be engaged in some way in the project design process – that can range from active involvement in the planning or implementation process to being kept informed about the process and plan. How to engage each stakeholder will greatly depend on their level of involvement, the impact they may have on our plans, and the impact our plans may have on them.

The goal of involving as many of the right stakeholders as possible is to achieve a truly participatory process, which should lead to greater community support and buy-in, more ideas on the table, a better understanding of the community context, and, ultimately, a more effective outcome.

To gain all the advantages of engaging in a participatory process, you have to figure out who the stakeholders are, how they should be engaged and at what level, and what issues they may bring with them. However you design your process, the Stakeholder Engagement Toolkit[1] will help you to identify stakeholders who need to be involved and consulted at different project stages.

A special note on engaging vulnerable communities and stakeholders

The most vulnerable individuals in a community may be the least empowered and most difficult to engage with; identifying and including them in a participatory process to fully consider their perspectives requires special consideration during ethical review processes. It may be necessary to devise separate or alternate ways to engage these groups, as other stakeholders within a community may have an interest in maintaining power structures and marginalizing or downplaying the impact of these populations in intervention design. These groups may include racially or socioeconomically marginalized, certain religious minorities, women, children, persons with disabilities, LGBT+ communities, and others. While it is often challenging to reach out to and hear from these groups, failing to do so can lead to serious gaps in your reach and effectiveness.

Sustaining stakeholder engagement

Bringing people and organizations into the process and keeping them involved and informed is extremely important. New stakeholders may need to be brought in as time goes on. Old ones may cease to be active stakeholders, but may retain an interest in the plan. It takes ongoing effort to maintain stakeholders' and supporters' motivation, keep them informed, and/or keep them actively involved. Stakeholder engagement can be maintained by:

- Treating them with respect.
- Providing whatever information, training, mentoring, and/or other support they need to stay involved.
- Finding tasks or jobs for them to do that catch their interest and use their talents.
- Maintaining their enthusiasm with praise, celebrations, small tokens of appreciation, and continual reminders of the effort's accomplishments.
- Engaging them in decision-making.
- Employing them in the conception, planning, implementation, and evaluation of the effort from its beginning.
- Recognizing where a given stakeholder's interests and energies lie, and allowing them to participate where and when they are best able.

1 Adapted from Community Tool Box (2019).

Informed consent and depiction of communities

Both research and the capturing of images and stories from a community are a form of "taking" proprietary information from the community, and should be done with the utmost respect for human dignity and the full and informed consent of community members. To avoid ethically problematic situations:

- Community participation in developing and implementing project protocols, activities and monitoring is encouraged to the extent possible.
- Outside organizations must do their utmost to ensure that their representatives treat people with dignity and respect. Stories should be told in the voices of community members, rather than about them, whenever possible, and images should be taken which maximize self-respect, human dignity, and community values. Where data/stories/images are used to communicate difficult circumstances, it is imperative that these be truthful portrayals, not manipulated or taken out of context, and shared with the consent of the individual or community. Portrayals that perpetuate stereotypes of victimhood or colonialism should be avoided at all cost.
- Participants should receive clear information about why their information or image is being captured, and should have the right to refuse to participate. People should be comfortable with the process and happy for their stories and data to be taken and used. It must be made clear if data or images will be used widely and internationally. It is often unreasonable to assure participants that they will be able to review any future use of data or images, and promises should not be made in this regard unless they can be kept.
- Informed consent is critical for all participants whose data are being captured. Many people will agree to participate without a full understanding of what data or images will be used for. There is often not an equal power relationship between external organizations and community members. People may feel unable to refuse a request in case it jeopardizes the project. People's full understanding of what they are consenting to is more important than written consent. Requests for consent must be carried out in local languages.
- Local hierarchal structures should be respected to ensure that consent is requested from the correct people. Family consent should be requested if required, especially of young children.[1]

We should also be mindful that even when gathering material is culturally acceptable in one place, it may not be acceptable to show it in another. Extreme care and sensitivity should be used when documenting taboo practices or stigmatized populations. Staff must also consider that some questions may be inappropriate or offensive. If in doubt, check with local staff or trusted local partners.

1 Adapted from WaterAid (2019).

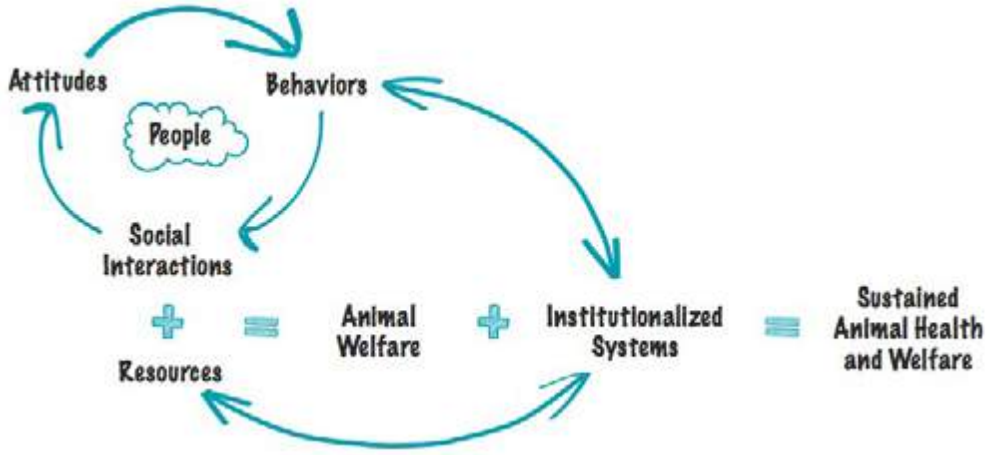
Note: To address some of these issues, international development and humanitarian NGOs have produced guidelines, such as the* Code of Conduct on Images and Message *(Dóchas 2007):

1. Choose images and related messages based on values of respect equality, solidarity, and justice.
2. Truthfully represent any image or depicted situation both in its immediate and in its wider context so as to improve public understanding of the realities and complexities of development.
3. Avoid images and messages that potentially stereotype, sensationalize, or discriminate against people, situations, or places.
4. Use images, messages and case studies with the full understanding, participation, and permission of the subjects (or subjects' parents/guardian).
5. Ensure those whose situation is being represented have the opportunity to communicate their stories themselves.
6. Establish and record whether the subjects wish to be named or identifiable and always act accordingly.
7. Conform to the highest standards in relation to human rights and protection of the vulnerable people.

Project sustainability

While some projects are intended to be short-term and carry short-term impacts (trialing a new veterinary drug, for example), others are designed to have longer-term effects on animals and/or communities. Many projects in the latter category have produced positive impacts but failed once the external partner has exited. Often, it is not merely the financial resources, but the skills, motivation, or adaptive management capacity that leads to project demise. This is an ethical concern because communities may have shifted their own internal organization, expectations, or practices to accommodate the project, and may not be able to return to their old ways of coping when a project fails. Further, each failed community project can lead to fatigue amongst communities, making it more difficult for future partners to build trust and partnership toward positive community outcomes.

If a project is intended to produce positive, lasting change in the community without consistent external inputs, then project sustainability needs to be planned from the outset, including sustained resources, systems, skills, and motivation to maintain the project. This means ensuring that the intended outcomes of the project are understood and desired by the community, and that plans are in place to ensure that the community has the skills, resources, and systems in place by the time your project is finished. It can be helpful to conceptualize the community's "final state" in a Theory of Change (*see sidebar below*), which shows the necessary steps to achieving project outcomes, and will also make clear what the community will be responsible for maintaining.



In the International Fund for Animal Welfare's (ifaw) community-based companion animal welfare theory of change, the interplay between owner behaviors, resources such as food and veterinary care, and community governance are shown. While engaged owners and adequate resources can result in better animal welfare, these conditions cannot be maintained without systems ensuring that the resources remain available, and that owners continue to be motivated to provide good animal care. Governments can maintain these pressures, and conversely people must sufficiently pressure their government to do so. By linking these key aspects of programming in a diagram such as this, it becomes clear that no single piece of the system can be missing at project's end if the outcomes are to be sustainable.

Too often, "capacity building" efforts, while well-intentioned, focus only on skills or resource sustainability, such as veterinary equipment and training. However, without resilient local systems in place to manage the project and adapt to changing conditions, and without sufficient motivation from the community and key actors, many well-designed projects or innovations die out once external actors leave. It is therefore important for sustainability that a wide array of stakeholders participate in the project from inception to completion to ensure that its benefits are shared widely, and that it is implemented in a way that works within the community's political and social networks. It is also important to recognize that the project may look different once managed by the community. Provided the same goals are being achieved, flexibility is encouraged.

Some key ways to ensure sustainability include:

- ***Establish a clear, shared vision with community stakeholders.*** Check in regularly to ensure that this vision remains a shared priority. If priorities have changed, adapting the project goals or duration may be necessary for sustainability.
- ***Plan for sustainability during project planning.*** Be clear about the intentions of the external parties to exit the project. If new infrastructures, skills, personnel or other activities are planned, make it clear to all stakeholders at the outset that these will

need to be maintained once external resources have left. Create a plan to ensure this happens for each element of the project. Do not be surprised if communities, especially those experienced in working with external donors, do not take this seriously at first. Be consistent and place responsibility in the community as much as possible, as early as possible, while also recognizing that it takes some time to build momentum.

- ***Involve and communicate with key stakeholders in project implementation and evaluation.*** This will help ensure that project activities work within realistic local constraints and conditions, and that lessons learned are incorporated into a resilient project design. It is important to provide regular opportunities for stakeholders to participate, even if, for some, participation is as minor as attendance at community events or engagement in social media.
- ***If something isn't working well, stop and ask why – don't just insist that things be done in a certain way.*** Often, unseen barriers, which might have seemed minimal during planning, are slowing the project. Perhaps key volunteers find that project activities impact their families' mealtimes, or a municipal employee has an uncooperative manager. In some cases, simple workarounds, such as purchasing climate-appropriate footwear for your volunteers, changing the timing of an activity, or reviewing project goals with decision-makers can solve the problem. In other cases, it is wise to accept that the local pace of life cannot adapt to the project's plans, and to find a different way to achieve the same goal.
- ***Mid-cycle evaluations to learn and adapt.*** During the course of the project, internal and external stakeholders will learn a great deal from one another. If communication is strong and the project responsive, it is likely the project will look quite different after its first year than it did in its plan. No shortcoming, in the first project cycle, needs to been seen as failure - these are merely opportunities to learn and adapt. It is important, during a mid-cycle evaluation, to evaluate what elements are contributing to a project's success. Do not forget to include human components such as management, training and re-training of personnel, communication, and information management. Make a list of who is currently responsible for each project element: Community member, local partner, or external partner. For any element reliant on parties that will be exiting, develop a realistic plan to shift responsibility to someone local. In some cases, this may mean changing expectations or re-working project elements to fit within local capacities.
- ***Create fundraising capacity.*** If financial or capital resources are a concern, begin helping the community consider options, including realigning local resources, exploring income-generating models, writing grant proposals, or developing new external funding partnerships and tourism opportunities, to name a few. These may require skills training, which needs to be planned during the course of the project cycle.

DESIGNING A COMMUNITY-BASED PROJECT

An ethical community project is one which is well-designed, is cognizant of the vulnerability and context of local stakeholders, aims to mitigate risks and maximize benefits to local participants, and results in monitoring-based learning and adaptive management. The following process, while always adapted to local context, can provide a rough guideline and checklist for research or project teams preparing to work with a community.

The project cycle

Most projects involving communities will have five main stages[1]:

1. Preparation and Site Selection:
   - Determine the exact purpose of the project.
   - Set criteria for communities that may be suited for the project.
   - Scope potential sites, usually guided by someone with local knowledge. This may involve preliminary meetings with stakeholders in potential sites to settle on the best candidate(s).
2. Community Social Impact Assessment – This stage will involve a more complete site assessment, including:
   - Stakeholder identification and engagement – are stakeholders sufficiently interested and available to participate in the project being offered?
   - Social impact assessment – What other social issues and priorities exist in the community? Do the benefits of engagement outweigh the risks to the community?
3. Project initiation and planning with stakeholders:
   - Establish project team and build rapport.
   - Project/study objectives and design agreed amongst stakeholders.
   - Planning mitigation for risk factors identified and incorporating safeguards in project design.
   - Planning communication and monitoring strategies.
   - Planning for sustainability.
4. Implementation stage:
   - Additional baseline research, where necessary.
   - Implement (adaptive) management and monitoring plans, including clear roles and responsibilities.
   - Implementing risk mitigation strategies.

1 Adapted from the Secretariat of the Convention on Biological Diversity (2004).

- Implementing internal and external communications strategies.
- Managing for sustainability.

5. Monitoring, Learning, and Exit:
   - Monitoring and sharing evaluation results with stakeholders.
   - Communicating outcomes with local and external stakeholders to ensure maximum learning.
   - Outcomes used to revisit original plans and revise based on learning and adaptation.

- Ensure sustainability plan is complete. Be clear about what support will be available to project stakeholders after external partner (or research team) exit.

Preparation and site selection

The initiating project team should determine:

- ***What are the goals of the project?*** It will be helpful to refer to the specific purpose later, when new opportunities, risks, and challenges threaten to re-focus the project.
- ***What outcomes are desired?*** What is the hypothesis being tested? Is it that a certain type of intervention can improve dog or cat care? That one treatment is more effective than another in a particular environment? What is the desired outcome for the community involved?
- ***What basic project design can evaluate these outcomes?*** In the case of research, this may be a complete design for the intervention. In most cases where a novel intervention is being trialed, this is not a complete project design, but it usually means having in mind the parameters and rough design of the project so that this can be communicated during next steps. In a completely participatory project, this step would come later—after site selection and community engagement—but the reality is that most donor-driven or research-driven interventions already have some parameters into which the project must fit. If so, these must be articulated up front.

Criteria

Next, the project team will need to draw up a set of criteria for ideal project sites. These may include:

- Presence or absence of certain thematic or cultural attitudes (for instance, styles of or attitudes toward keeping domestic animals).
- Political structure and willingness of community to engage in potential solutions.
- Geographic location.
- Social stability.
- Accessibility.
- Fundraising potential.
- Presence/absence of certain resources.

If the project is intended to have sustainable outcomes, it is also wise to consider here

the types of communities likely able to sustain the intervention. A technical veterinary intervention is, for instance, not advisable in a remote community with little to no veterinary access.

Scoping

Based on the criteria selected, the team should determine several potential sites for scoping. For each project site required, two to three communities may need to be assessed.

Local team

The team will need to recruit local team members for community engagement who possess the following traits:

- Knowledge of and experience working in the environment targeted for the intervention
- Local language skills
- Rapport building and (formal or informal) facilitation skills.
- Respect for animal welfare and ethical research.
- Flexibility and resourcefulness.
- Competency in and comfort with the language of the external team, and familiarity with the communication method and style of the external team (e.g., email, SMS, Skype, etc.).

These local team members will be the literal and cultural translators for the external team, so it is important that they are integrated well into the external project team and allowed to understand the goals, skills, and limitations of the external partner. They must also be able to spend time within the intervention community, often informally, building connections and trust.

Site selection

In collaboration with the community engagement team, initial outreach takes place to formal community leaders and any key players in animal welfare or those affected by animal concerns (such as teachers, animal owners, health services, cultural leaders). Assessment at this stage is usually informal and should seek to determine which site(s) best fit the site selection criteria. This may be done through a community meeting, where such meetings are common and practical, but is usually done through conversations or meetings with leaders that seek to determine:

- Does the community meet the project criteria?
- Is the community welcoming of a project/intervention?
- A basic understanding of how key players in the community view their animals, key concerns about them, and desire for change in the situation.

It may also be helpful at this stage to try to learn more about:

- Similar projects or interventions that have been tried previously.
- Any external issues or threats to the community's well-being that could overshadow the project (e.g., upcoming

CASE STUDY

Stakeholder group challenges: Unspoken concerns and skills limitations

A small eastern European city was having challenges with a sizable roaming dog population in its town center. In response, the municipality opened a shelter, although limited funding meant that in reality this was little more than several doghouses in an unpopulated area to which unwanted dogs were chained permanently. When the mayor and key municipality staff requested assistance from an international NGO to better manage their dogs, it was agreed that they would try an approach that led a wide-ranging group of citizen stakeholders through a sustainable planning process, rather than having the NGO perform short-term services.

The group, which consisted of dog owners, dog lovers, veterinary authorities, teachers, police, and other municipal stakeholder group representatives, were enthusiastic, and municipal leadership supported the efforts of the group to outline their key challenges and how they wanted to resolve them. However, planning stalled when the community kept coming back to the issue of the shelter. Although some thought it was helpful, most stakeholders simply felt sad about the way the dogs were treated and found themselves unable to enthusiastically support any new measures until that was addressed.

The international NGO partner saw an opportunity to build enthusiasm in the community by taking positive action. They agreed to help rehome the shelter dogs, on the provision that the community never undertake this type of sheltering again, that no new dogs were to enter the shelter, and that the municipal vet provide papers and vaccinations to facilitate international rehoming. This was documented in a written agreement, after which the municipal vet, on which all action hinged, made no progress. After nearly a year of stalled progress and losing community momentum, the international NGO agreed to a modified process, where they would help the vet to assess and vaccinate the dogs. In doing so, they came to realize that the vet had little or no formal training with dogs, and was afraid of them.

Through patient but respectful mentoring, the vet, who initially stood as a barrier to the process, became an ally and a champion. Eventually, all of the dogs were removed and rehomed, with the NGO ensuring that the local vet, the volunteer team, and the Mayor received most of the credit.

This show of support for the community's wishes, as well as respect and mentoring in critical skills, left the community more capable and confident about pursuing their dog management goals. Progress on the remainder of their plan proceeded quickly. An active volunteer team, supported by the mayor and the municipal veterinary office, continues to care for, foster, rehome, and advocate for the humane treatment of dogs in their city.

elections, major infrastructure projects, disease outbreak, etc.).

- Other key social issues in the community, e.g., socioeconomic divisions, social tension, points of cultural or social connection, and livelihoods.

This information should be presented to the project team for final site selection. Once selected, it is important for all parties to be clear about the scope of the community, as geographic boundaries are not always clear. Scope may include or exclude outlying settlements, additional domestic species, certain socioeconomic populations or seasonal variability within the community, or other accommodations as needed to address the community's reality. Clarity around scope early in the project is critical to mitigate challenges later in terms of managing budget, monitoring, and reporting impact.

Note: It is very important at this point to not make any promises to communities unless their participation is guaranteed. During this scoping phase, it is wise to remain open-minded and pursue less formal communication if a formal meeting will imply aid or assistance that the community is eager to receive.

Once a site is selected the team should hold a formal meeting with community leadership and/or a stakeholder group to outline the scope of the project. The community engagement team should always be clear how much community participation in the design and implementation of the project is anticipated. Any specific requirements of the community (e.g., agreeing to abstain from certain practices, such as culling) should be clearly laid out at this time. Any key requirements from the community should also be noted and respected. This may be laid out in a formal agreement or MOU where locally appropriate. Where significant community engagement is anticipated in project design and implementation, this stage is usually relatively short, establishing goals and project parameters, but leaving detail open for participatory design.

Community social assessments

Stakeholder engagement

The project team can now determine the key actors in the community who will be involved in the design, steering, implementation, monitoring, and communication about the project. The team may utilize the Stakeholder Engagement Toolkit to determine which stakeholders exist in the community and how best to engage them. Based on this assessment, it will become clear whether a group-based participatory research and planning process is feasible, or if a consultative strategy involving smaller groups of stakeholders should be undertaken (e.g., engaging leadership, women's groups, neighborhood groups, informal groups, and certain individuals separately).

Social impact assessment

At this stage, a Social Impact Assessment (SIA) should be conducted, with the authority of the agreement made in the previous step, and usually with the participation of key stakeholders. A SIA is a process for the identification, assessment, management, and monitoring of the social impacts of a project, both positive and negative. Some version of an SIA is used widely across industry, environmental, and development fields. By completing an SIA, the project team should seek to establish a strong understanding of the current status of a community's relationships with their animals, with their environment and with each other, and any unintended consequences or opportunities the project may have to incorporate in its planning. This may look similar to initial community scoping, but will be undertaken more formally with results documented. It may be conducted in the form of community surveys, focus groups, interviews, or a combination of these.

A Social Impact Assessment will seek to determine:

- What is life like in this community? In what areas are people struggling and in what ways are they doing well?[1]
- What are the sources of livelihoods in this community?[2]
- What are the main social challenges in this community?
- In what ways does this community express its cultural values, norms and sense of connectedness to each other and the environment?
- How does this community interact with its dogs and/or cats? What benefit is derived from these animals? What challenges do they cause?
- What are the specific challenges to men, women, children, and minority or less advantaged groups, including socioeconomic divisions?
- Would the project likely change the way any particular group interacts with its dogs and/or cats?
- Would the project impose risks to any particular group or risk upsetting community social cohesion or livelihoods?
- Could the project provide opportunities to address current vulnerabilities in the community, which can be enhanced if planned properly (e.g., capacity building, infrastructure, or education opportunities)?

1 Impacts of development projects are often viewed through the lens of the Sustainable Livelihoods Framework (DFID 2000), which focuses on the means for people to provide for themselves. Alternatively, they can be viewed through lenses such as the UN Sustainable Development Goals (2018) or a well-being index such as Gross National Happiness (Centre for Bhutan Studies and GNH, ND), both of which are framed primarily in terms of positive impacts. While dogs and cats and a community's interactions with them may seemingly play a minor role in these systems, it has been shown that a community's health, safety, well-being, social relationships, physical space and infrastructure, sanitation and income may be negatively or positively affected by the condition and status of dogs in the community (Atema & Arluke, 2015). As this touches on every type of livelihoods capital, it is necessary to consider each of them when considering an intervention which may impact the interactions with dogs and cats in a community. It will be important to first be able to put into context a community's current, and desired, state of living with its animals, as well as the attitudes driving current management strategies.

2 A livelihood comprises the capabilities, assets (including both material and social resources) and activities required for a means of living. A livelihood is sustainable when it can cope with and recover from stresses and shocks, maintain or enhance its capabilities and assets, while not undermining the natural resource base.

- What social impact risks and/or opportunities should be monitored during the project to expand its definition of impact?

Results of an SIA can be used to better plan and monitor a project by utilizing the following steps:

1. Determine which stakeholder groups are likely to be impacted by the project.
2. For each group, based on an understanding of community power structures, decision-making, and social and cultural systems, determine what negative and positive social changes or impacts may result from the project and/or its alternatives.
3. Establish the significance of the predicted changes (i.e., prioritize them).
4. Identify ways of addressing potential negative impacts (e.g., avoid, mitigate, compensate).
5. Develop and implement ways of enhancing benefits and project-related opportunities.
6. Develop indicators to monitor change in these social indicators over time.
7. Include risk mitigation, benefit enhancement, and social monitoring in project plan.

Social Impact Assessment Themes

For larger communities or more involved projects, a more formal community assessment may be warranted. Thematic sections recommended for a formal social impact assessment include (Wilson, 2017):

1. Regulatory framework (relevant international standards, national/regional legislation, sector-specific legislation, customary law).
2. Administrative divisions and governance structure (national, regional, local levels of governance, international relations).
3. Population/demographics (gender/age/ethnicity, migration trends, religion, vulnerable groups).
4. Economy (employment, key sectors, business environment, financial services institutions, labor rights/working conditions, informal livelihoods, income, poverty/inequality).
5. Infrastructure (utilities, electricity, telecommunications, waste management, housing, transport infrastructure, markets/trade links, recreational facilities).
6. Community health, safety, and security (health of population, mortality rates, health services, water/sanitation, road safety, fire services, disaster management services, police/security services, access to justice).
7. Education (literacy, education levels by gender, education, and training institutions/services).
8. Social problems (crime, alcohol/drugs, prostitution, child/forced labor, employment inequalities, social tensions and conflict).
9. Land tenure and use (types of land and natural resource use, water use and availability, private/customary forms of use and ownership, types of agriculture/livestock ownership).
10. Cultural heritage (archaeological finds, indigenous sacred sites, historical buildings).
11. Civil society (trust, civic involvement, press freedom, freedom of association, civil society activism, trade unions, mass media, social media, indigenous rights groups, environmental groups, non-governmental community support organizations).

PROJECT INITIATION

Establishing a project team and building rapport

With the assessment of stakeholders and a clear understanding of how the community works and may be impacted by the completed project, the project team must spend the time to build a sense of true partnership with the community, which, depending on the context, may be undertaken in formal meetings, or may be done through a series of informal discussions.

Sometimes, this stage is fairly straightforward; other times it requires extensive engagement, time spent in the community, and in some cases, building trust in the community by engaging in a mutually beneficial activity, such as offering training, a token animal-related service, or other demonstration that the project team is genuinely invested in the community.

Care must be taken at this stage not to set expectations of free service provision or of providing resources which cannot be sustainably supported in the long-term. Many communities are familiar with external agencies and exploit this stage in the relationship to receive services and goods. This stage is about building positive working relationships, so activities need to be chosen with care to reflect the values of the project as a whole, while moving quickly enough to demonstrate the intent of the external partner to follow through on commitments.

When a clear group of individuals are comfortable and willing to discuss plans with the external project team, it is time to continue.

Project objectives and design agreed amongst stakeholders

In a participatory setting with community leaders, or with the local steering group given authority by the community, project values, risk mitigation, and implementation strategies should be established.

The formality and format of discussions and agreements will depend largely on culture and context. If appropriate, they should be documented in a memorandum of understanding (MOU) or other written agreement format with the community.

However determined and documented, the project team should ensure that all parties are clear on the following points:

- Shared goals and cultures in the community, and respect for the values of the community and the project partner.
- Interests of the community and external party in the project.
- Familiarity with issues the community might experience related to the project rationale, purpose, or scope.
- Outline of the goals, activities, and timeliness within the scope of the project.
- Contributions of capital requested from each party.

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- Partners in the community that can represent the community's interests.
- Potential risks and benefits associated with stakeholders' participation (to individuals and the community as a whole).
- Processes to obtain meaningful informed consent/permission.
- Community involvement in the planning process.
- Potential uses of collected data, and plans for dissemination and sharing with the wider community. Include a process for managing project findings that reflect negatively on and may cause harm to the community.
- Opportunities for the community to review and add questions to data collection methods that are important to them and relevant to the project.
- Acknowledgement of the contributions of the community in publications and presentations, and encouragement to participate in their creation (opportunities for co-authorship).
- Training provided to community members to help promote the project within the community.
- Opportunities for community members to learn additional skills, gain experience, and build capacity throughout the project.
- Identify and encourage application to appropriate funding sources to help with capacity building and sustainability of interventions.

Planning for sustainability

It is imperative, if a project is intended to be sustained once the external party has exited, that sustainability be planned from the beginning. This means assuring that every project element (including planning, implementation, data collection, and evaluation, as well as budgeting, communication, and other "behind the scenes" roles) has a point person or agency with the skills to maintain them once the external party has gone. Each element

CASE STUDY

Stakeholder engagement leads to stakeholder action

In a southeast Asian country with a large owned-roaming dog population and endemic rabies, dog culling was a fairly common response to local rabies cases, even though there was a regional rabies vaccination program in place. Local villages, who feared rabies but had little knowledge otherwise about the disease, felt powerless to manage the situation and reluctantly allowed their dogs to be poisoned by government teams following a rabies case.

Realizing that villages might have the power to request or restrict the culling, one group decided to try a different approach to their rabies campaigning. They held a community meeting to listen to people's concerns about dogs in their village, and requested the agreement of the villagers to join in a program to help keep their dogs healthy and rabies-free. Instead of offering large-scale free veterinary services, the program started by spending significant time in the community, getting to know dog owners and their families, so they could better understand what prevented people from keeping their dogs healthy.

They spent many hours in the community every month, answered questions, provided support for minor veterinary challenges such as parasites, and helped engage dog owners in conversations about ways to keep their dogs healthier and build better relationships with them. In time, community members themselves were requesting support and information, and many began to form "dog lover clubs" to get together and share knowledge. They organized sterilization and vaccination events, and helped ensure that the dogs in their village stayed healthy and rabies-free.

When rabies cases began to emerge in this region, the government again came with teams to poison dogs. However, the villages with local dog clubs all escaped the culling. They were able to do this because their dogs were healthy and in many cases escaped the attention of culling teams, but also because in some cases villagers actively prevented the government teams from entering their streets and homes. These communities felt themselves to be an active part of the community dog program, and therefore felt empowered to take action when needed.

should be assessed for both its current and ultimate community "owners," and how those parties will be prepared for their respective new responsibilities.

Note: In planning sustainable projects, the following principles can be applied:

1. Hire locally whenever possible for project services, and when not possible, cultivate the workforce you need from within the community. Buy supplies (including food, uniforms, etc.) locally whenever possible, and consider building enterprises from which to buy if they don't currently exist.
2. Focus capital inputs around communal goods, e.g., schools, central water sources, community enterprises, and veterinary clinics, and ensure equal access to benefits.
3. Do not build or create anything that cannot be sustained without outside support, unless that support is guaranteed for the long-term.
4. Avoid giving anything (including small tokens of kindness) that would undermine local enterprises, e.g., clothing or food which can be bought or made locally. If veterinary services are to be provided for free or a subsidized rate, local veterinarians should be included in the project team and/or clearly understand how the target project population differs from their clientele.
5. Be transparent about your goals and values from the outset. These are then built into a joint project to which the community contributes, building partnership around shared goals.

IMPLEMENTATION STAGE

At this stage, additional baseline research may be needed to determine more clear and specific baseline values for project targets. This research would ideally be carried out by community members, and the outcomes shared within the community.

Implementation incorporates all of the elements from the collaboration, planning, and preparation that went into the previous stages. The better the preparation, the more straightforward implementation will be. It is imperative that clear roles and responsibilities are delineated, particularly point persons responsible for making decisions about discrete project elements.

During this stage, it is likely that adjustments will need to be made on everything from minor logistical issues to addressing incorrect assumptions or things that simply are not working. The core project team should meet on a weekly basis and establish other forms of formal and informal communication so that the project can be adaptively managed, even during the first project cycle.

Formal communication to the community and wider stakeholders also needs to be planned

on a regular basis. It is important to have a communication plan and to stick with it in order to ensure the wider support of the community, enable new stakeholders to emerge, and make sure that detractors can have their concerns addressed and see progress.

Where communities have committed resources, they must be allowed to contribute these and claim the credit and pride for doing so, even when this may slow the implementation process. While the external project partners are likely key contributors early in the implementation cycle, this is the stage when sustainability plans must also be implemented, allowing community actors to take over project tasks, management, and decision-making, which ultimately provides the momentum for the project.

The first project cycle comes to a close when monitoring is completed and the first round of project-level data have been collected. At this stage, the project team, including local stakeholders, should come together to assess whether the project has met its targets (including social targets, where included), and to reflect on the process, teamwork, adaptations, and learning that have occurred so that these can be built into the next project cycle.

MONITORING, LEARNING AND EXIT

Monitoring and evaluating project outcomes is a critical element of an ethical community project. When putting people and animals at risk, however minor the risk may seem, it is imperative that the results of the project are shared, in ways that are clear and accessible, with project stakeholders and others who may benefit from the learning (positive and negative) that occurred during the project.

Monitoring and Evaluation is dealt with separately in the **Data Collection and Use Toolkit**, but can provide the basis for project communication, learning, and trust-building with the community partner. Often, a participatory evaluation event offers a great way to allow stakeholders to digest data and share their experiences of the project in their own terms. Through effective monitoring, evaluation, learning, and communication, it can be assured that communities contribute positively to, benefit from, and have a positive experience with the innovation in which they were subjects and participants.

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BACK

STAKEHOLDER ENGAGEMENT TOOLKIT[1]

STAKEHOLDER IDENTIFICATION & ANALYSIS

Identifying stakeholders and their interests is among the very first steps in the community engagement process (see also the Communities Toolkit) because the knowledge of local stakeholders and understanding of community needs is essential to the potential for success.

The process of stakeholder identification and analysis can help you to discover some unlikely allies and identify unexpected opposition. Engaging both supporters and dissenters is critical to developing solutions and a plan that will have the broadest possible acceptance and the best chance of success.

When engaging stakeholders, you will be asking:

- Who should be involved?
- Why should they be involved?
- How should they be involved?

Not all stakeholders are the same. Some will be helpful when gathering community information in the early stages, for instance through participatory research. Others will be involved in planning the project and setting out guidelines. Still others will be more involved later in the process for building a strong, local implementation team.

If you are in the early stages, the stakeholder prioritization and research process does not need to be as in-depth – it is more important to engage a wide audience representing different sectors of the community until your project is more focused and ready for planning.

As you go, you may need to revisit the stakeholder identification process to revise your stakeholders and update your plans with your greater in-depth understanding of the community.

STEP 1: WHO SHOULD BE INVOLVED?

The first step is to brainstorm a comprehensive list of stakeholders, which should include every conceivable stakeholder; every person, group, or organization that can affect or be affected by your actions, plans, objectives, and policies.

Ideally, several people, including local team members and/or community contacts, should be involved in brainstorming and analyzing the list of all the possible stakeholders from every possible section of the community. It is helpful to think about who should be on the list from different perspectives because it can identify stakeholders who might not be

1 Much of the information in this toolkit has been adapted from the Community Toolbox, a service of the Center for Community Health and Development at the University of Kansas. More information is available at: http://ctb.ku.edu/

immediately obvious and who can bring added value.

Using sheets of paper or sticky notes, each person should write down every stakeholder they can think of. Try to be as specific as possible about the individual contact person/people for each stakeholder/stakeholder group.

Write one stakeholder/group per piece of paper/notes. Sectors that you will want to consider will likely include but not be limited to:

- Government departments and key officials
- Law enforcement
- Health
- Animal owners
- Veterinarians
- Animal welfare groups
- Business owners
- Youth and Women's groups
- Neighborhood or village associations
- Religious leaders
- Media
- Academics/schools

STEP 2: WHY SHOULD THEY BE INVOLVED?

If your goal at this point is solely to scope the community or get a baseline understanding of the values and perspectives of the community, you may stop here and try to engage all of these stakeholders.

Getting a broad baseline through, e.g., focus groups or participatory workshops, can be a helpful step before you proceed into detailed project planning and implementation. See note on participatory stakeholder engagement, below.

However, if you have moved beyond initial engagement and are ready to find the stakeholders you need to work effectively in the community, it's important to do some analysis to determine who among stakeholders can have the influence, positive or negative, on your project and who is likely to be most affected by the effort.

Create your own stakeholder mapping matrix, similar to **Table 1** on the next page. Assign each stakeholder to the appropriate section of a grid based on your assessment of their influence on and interest in your project.

- **Interest: low or high?**
  How much will this stakeholder be impacted by project planning and actions? This is not about whether they will like or dislike the project, only about their interest in the topic - positive or negative.
- **Influence: low or high?**
  How much power does the individual or group have in the community? Can they influence others' actions or opinions?

Table 1: Stakeholder Mapping Matrix

High Influence, Low Interest: What's in it for me? Collaborate and show how your project helps meet these stakeholders' own goals	**High Influence, High Interest: Project Champions** Involve these stakeholders in planning, implementation and monitoring. They can drive change and make it happen.
Low Influence, Low Interest: Extended Networks Keep these stakeholders informed through public communications and outreach. They play an important role in understanding your project baseline and a reinforcing role in the community conversation about your project.	**Low Influence, High Interest: Energy Source** Use these stakeholders as much as possible for implementation tasks, energy and outreach to their community. Be sure to involve them, but establish firm protocols to keep project on its intended course.

In the stakeholder matrix chart above, low to high influence runs along a line from the bottom to the top of the grid, and low to high interest runs along a line from left to right. Both influence and interest can be either positive or negative, depending on the perspectives of the stakeholders in question.

INVOLVE (High influence, high interest)

A successful participatory process may require that the people with the highest level of influence and interest (the promoters) understand and buy into the process fully. They can then help to bring stakeholders in the other positions on board, and to encourage them to participate. Stakeholders that are very interested and very influential can really make the plan move forward because they care about and are invested in the issue. If they are positive, they need to be cultivated and involved. These are the stakeholders you need on your planning team, helping to set project guidelines, make decisions and communication. Find roles for them (not just tasks) that they will enjoy, and that contribute substantively to the plan, so they can feel responsible for part of what is happening. Pay attention to their opinions, and consent to them where it's appropriate.

When people who could be promoters are negative, the major task is to convert them. If we can't, they can become the most powerful opponents of our plans and could make it impossible to succeed. Therefore, they need to be treated as potential allies, and their concerns should be addressed to the greatest extent possible without compromising the plan.

Often: Veterinarians, teachers, public safety and informal community leaders

Keep informed (Low influence, Low interest)

These stakeholders don't care much about your project and have little influence over whether it is successful, but they probably have opinions and experiences with the topic anyway, and these should be noted.

The plan may in fact have little or no direct impact on them. As members of the wider community, however, you know that if they are on the right message, then the message has really gotten through.

You can keep them informed in whatever ways the community typically shares information. Don't offend them, and they won't bother you or get in the way.

Often: neighborhood groups, medical community, business community, religious groups, agricultural workers and others.

COLLABORATE (High influence, low interest)

Stakeholders that are very influential but not very interested. These are people and organizations who could potentially be extremely helpful, if they could be convinced that the plan is important either to their own self-interest or to the greater good. We must approach and inform them, and to keep contact with them over time. Offer them opportunities to weigh in on issues relating to the plan and demonstrate to them how the plan will have a positive effect on issues and populations they are concerned with. If we can shift them over to the promoter category, we have gained valuable allies.

There is the possibility that these people could be oppositional. If that is the case, it might be best not to overly engage them. If they are not particularly affected by or concerned about the plan, even if they disapprove of it, the chances are that they will simply leave it and you alone, and it might be best that way.

Often: Municipal governments, health departments and business or religious leaders

Engage (Low influence, high interest)

We might think that people and organizations that are very interested but not very influential can't help much, so you can simply keep them informed and not worry too much about involving them. However, these highly-interested stakeholders can often provide the volunteer time and skills that any plan – particularly an advocacy initiative – needs to survive.

These are often the foot soldiers who stuff envelopes, make phone calls, and otherwise make an initiative possible. They are also often among those most affected by a plan, and therefore have good reason to work hard for or against it, depending on how it affects them. When they feel left out, or slighted, their energy for the issue can result in major backlash and misinformation, so it is best to ensure these groups feel that their concerns have been heard and incorporated early, to give them specific jobs within the plan that address their interests, and to allow plenty of time to listen and acknowledge them.

Often: Youth, animal welfare groups or lone activists, mid-level municipal or business employees, and the "information spreaders" in the community (via Facebook, gossip, media or other local means of spreading news).

STEP 3: HOW SHOULD YOU INVOLVE THEM?

For each stakeholder that you have prioritized as requiring a high degree of engagement, it is essential to gather more information about that stakeholder, in order to approach them the right way and keep them engaged. The following is some of the information you will want to understand through formal or informal research into your key stakeholders.

Interest level:

- What experience does this stakeholder have with this issue?
- Do you believe they would be positive or negative about the project initially?
- What might they want or expect from the project team?

Influence:

- Who do they influence – who listens to them?
- Is their influence formal or informal?
- Whom do they listen to?
- If an organization, what is the reporting structure?

Opportunities:

- What are their skills and abilities to participate in planning or implementation?
- Are there gaps in their skills, knowledge or resources that provide us with opportunities to support them?

Engagement:

- How can they help the project?
- How could they hurt the project if they were disengaged or opposed?
- How do they like to communicate? In person, via social media? In print or by voice?

Based on the research you conduct, make a list for each key stakeholder:

STAKEHOLDER NAME_____		
During which project stage should you engage them?	☐ Initial assessment ☐ Planning ☐ Implementation ☐ All of the above	Notes:
What is the best way to engage this stakeholder group or representative?	What roles or tasks would best involve and suit this stakeholder?	Notes:
Who is best placed to communicate, and via what method?	☐ Online ☐ In writing ☐ Face-to-face ☐ During participatory workshops	Notes:
How often to communicate? For example, do they need a formal update monthly? Can you just keep them updated regularly, or via an annual check-in?	☐ Daily ☐ Weekly ☐ Monthly ☐ Annually ☐ Form ☐ Informal	Notes:

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A note on Participatory Stakeholder Engagement

Prioritizing stakeholders by analyzing how much they can help with your project is critical to achieving organizational goals, and is always useful – especially during later project stages of detailed project planning, implementation, monitoring, and communication. In the early stages, however, many communities respond well to group-style participatory engagement, i.e., a workshop-style meeting where perspectives are shared and/or a collaborative planning process takes place.

Participatory processes with broad stakeholder representation, when they are workable in the community, can be especially useful in uncovering key issues in the community and building consensus around broad project goals and strategies. They can allow the community to do more of the work in the early project stages, allowing project leaders to listen and learn more quickly. In this case, it is important to attract representatives of all stakeholders, regardless of their perceived interest or influence. The goal will be to treat all stakeholders as equals and colleagues, while at the same time leveling the field as much as possible by providing training and support to those who need it.

It is important to include stakeholders that are very influential, but skeptical, negative, or not very interested. The more people, groups, institutions, and organizations with influence that are involved, the greater the chances for success.

Often, engagement of marginalized groups through participatory processes can result in the interest of others who previously only understood their own perspective and/or were skeptical of the project. Providing opportunities for these groups to share their perspective with others can be particularly powerful if the listeners know the people involved, but never suspected the challenges they face. Your goal is to convince these groups that they are true stakeholders, and that the plan will benefit them either directly or indirectly.

Not all communities are good candidates for group-style participatory engagement. Extreme divisions in the community, i.e. socioeconomic, gender, or religious divisions that would make it uncomfortable for each group to share openly and honestly, may be reasons that this approach is not advisable.

Other communities are simply too busy to get together in one time and place. In these cases, simple stakeholder prioritization and a comprehensive outreach strategy as outlined above are the way to go.

Sustaining engagement

Once you have their interest, either through participatory engagement or a one-at-a-time stakeholder engagement strategy, it takes ongoing effort to maintain stakeholders' and supporters' motivation, keep them informed, and keep them actively involved. New stakeholders may need to be brought in as time goes on. Old ones may cease to be actual stakeholders but may retain an interest in the plan and may therefore continue to be included. You can help sustain stakeholder engagement by:

- Treating them with respect.
- Providing whatever information, training, mentoring, and/or other support they need to stay involved.
- Finding tasks or jobs for them to do that catch their interest and use their talents.
- Maintaining their enthusiasm with praise, celebrations, small tokens of appreciation, and continual reminders of the effort's accomplishments.
- Engaging them in decision-making.
- Employing them in the conception, planning, implementation, and evaluation of the effort from its beginning.
- In the case of those who start with little power or influence, helping them learn how to engage by working together and developing their skills and sense of value in the process.

REFERENCES AND FURTHER READING

The International Fund for Animal Welfare (ifaw) developed the Humane Community Development (HCD) framework as a way for communities to work together to find humane, sustainable solutions to dog issues resulting in negative consequences for people and animals. Learn more through IFAW's series of eLearning modules (available through the ICAM website: https://www.icam-coalition.org/tool/humane-community-development-hcd/) designed to introduce and help train community mentors and others on the HCD participatory approach to addressing dog population management in communities worldwide.


BACK

ADDITIONAL RESOURCES

SECTION CONTENTS

ETHICAL CONSIDERATIONS & QUESTIONS

Below are questions that may be relevant to a researcher, organization, or veterinarian when implementing a study (including a program, procedure, or research). The questions tacitly assume that studies involving animals can be conducted ethically. Therefore, the key consideration is how to intervene in the most ethical manner, especially when a study is novel within particular circumstances, and when the potential outcomes and risks or harms are not well known.

Questions assume that individual animals, dog or cat populations, and/or the broader animal community have the potential to benefit from the study. This is in contrast to research in which the individual animal and other individuals from the same species may never experience benefits. Given the "field" orientation, questions also assume that people and communities will engage in or be affected by the study, as well, in various capacities

Questions were originally developed with ACC&D's specific studies in mind: marking dogs in Kenya and evaluating a contraceptive vaccine in US cats. However, questions have been expanded with the goal of encompassing a broader range of scenarios with varied locations; resources available within a community and initiative; and degrees of invasiveness and risk/benefit to animals, people, and communities. Relevant questions and considerations from this list may differ according to the particular scenario.

We do not envision answering the questions below as the endpoint, but rather view the questions as a way for those involved to frame their own evaluations, and as a component of creating guidelines for field studies.

The issues to consider are set out in color-coded sections under the following headings:

GENERAL CONSIDERATIONS

PROJECT DESIGN, PROTOCOL, AND PARTNERS

ANIMAL WELFARE CONSIDERATIONS

HUMAN/COMMUNITY CONSIDERATIONS

GENERAL CONSIDERATIONS

- Who are the relevant primary stakeholders, including animals, and what are their respective interests.
- The nature of your responsibility to the individual animal, the owner, the community, and any other major stakeholders in the project.
- How you navigate responsibility to different stakeholders when there are competing interests.
- The responsibilities that other stakeholders have to animals, owners, and the community.
- Whether due diligence has been performed (e.g., through literature reviews) to establish if the project poses any unforeseen risks, is redundant, is likely to add benefit, or could be improved.
- Whether strategies to minimize the risk to the animal and community associated with a project have been fully explored.
- What are your criteria and thresholds for determining when it is more ethical to not intervene.
- Who are the appropriate and ultimate decision-maker(s) in addressing any question or issue regarding the project.
- How decisions will be implemented (e.g., how assessments will be made, and compliance encouraged/enforced).
- How the project's effectiveness/efficacy will be evaluated.

PROJECT DESIGN, PROTOCOL, AND PARTNERS

Data Quality

- Whether the project's decision-making processes, data quality, and data management are of a sufficiently rigorous design to ensure meaningful results and learnings—and if not, whether it is ethical to proceed.
- Whether a control group is warranted and acceptable and, if so, what that group looks like.
- The point at which a statistically significant result (and associated numbers of animals) is warranted in a research project.
- Whether or not all measurable indicators (e.g., population numbers and dynamics estimations) were included in the planning, conduct, and reporting of the results.

Funding

- Whether funding or other forms of sponsorship for the project influence the protocol and approach, and to what extent this sort of influence is appropriate and acceptable.
- Project partners and personnel
- The process for selecting partners and personnel with whom there is a strong working relationship and capacity for a mutually agreed upon set of ethical guidelines and standards.
- How to address a situation where those involved in a project disagree on any of the standards or protocols.

ANIMAL WELFARE CONSIDERATIONS

Standards of veterinary care

- What are the minimum veterinary standards for the project to proceed ethically.
- Whether the availability or standard of veterinary care differs between the community where the project is taking place and the community of those implementing the project. If there is a difference, the expectations of those who support the organization conducting the project might come into play.
- Whether veterinary care in the project needs to match or exceed the local standards—and if you want it to exceed, by how much.
- The veterinary care that must be available, and the protocol and safeguards needed, to addressing any adverse events.
- Whether veterinary care should be provided to participating animals for issues unrelated to the project, if they would not otherwise receive care.
- Whether veterinary care should be provided to animals in the community who are not in the project, if they would otherwise not receive care.
- The health and welfare criteria for excluding particular animals from the project.

Standards of animal handling

- The protocols and standards for handling animals as part of the project, and how those standards are enforced.
- How animal handling standards in the project must align with standards in the community of those implementing the project—and if local standards are lower, whether/by how much handling standards must exceed those in the project community.
- Whether any minimum (universal) standards should be in place regardless of local standards or those recommended by funders or other external stakeholders—and, if yes, what those standards are.

Minimizing/avoiding pain and distress

- The measures taken to ensure that animals experience minimal distress or pain.
- The level of pain and stress that is acceptable in light of benefits to the individual who is part of the project, as well as the broader animal community.
- How physical, psychological, and social harm are measured and evaluated in the project.

Complications

- The risks that animals in the project will face.
- The level of ongoing observation, assessment, and subsequent action needed to sufficiently mitigate the risks.
- The risk assessment and contingency planning strategies that need to be in place to conduct the project.

Individual animal benefits and welfare

- Whether all animals in the project experience similar risks, and whether intervention or absence of intervention will increase participants' vulnerability and risk.
- What the protocol is for objectively assessing vulnerable animals—and how to proceed with vulnerable populations.
- The benefits to the individual animal taking part in the project, as compared to the broader animal community.
- The harms or risks (physical, psychological, social) to the individual taking part in the project, as compared to the broader animal community.
- The levels of harms and risks that are acceptable for proceeding.
- The degree of potential benefit to an individual animal that is required to balance the potential harms to that animal.
- The standards against which "adequate" or "good" welfare for cats and dogs is measured in a project.

Endpoints

- The animal welfare criteria in place to determine whether the project should continue.
- The animal welfare criteria in place to determine whether an individual animal should continue participating in the project.

HUMAN/COMMUNITY CONSIDERATIONS

Spheres of input and authority

- Who/what comprises the "community" for the project.
- Who has responsibility or authority for animals in the project.
- Whether knowledge about responsibility for animals has been sought from representative local stakeholder groups (government/health authorities, veterinarians, animal activists, NGOs, etc.).
- The nature of the consent/permission needed to proceed in an ethical fashion, and how it will be obtained and documented.
- The actions needed to ensure that an individual animal guardian understands that they can decline or end participation in the project.
- The actions needed to ensure that consent is received from the correct owner(s) or guardian(s). Specific considerations include gaining permission when a minor is responsible for an animal, or when working with loosely owned or community-owned animals.

Format for informed consent or permission

- What informed consent/permission entails, and how they are documented.
- The level of transparency and detail about the project purpose and intentions that is necessary and ethical, and how it should be conveyed.
- The languages that are necessary to ensure that all stakeholders can prove informed consent/permission in written or verbal form.

Human-animal relations

- The roles that animals have in the community, and how this affects community support for the project and responsibilities of those implementing the project.

Compensation and incentives

- The compensation that is appropriate and effective for different stakeholder groups (e.g., participants, partner organizations, local volunteers and employees).
- Whether the community views the project as relevant or beneficial—and if not, whether it is ethical to proceed.
- Whether the participating community and animals will benefit from project results, particularly if research is conducted to benefit populations outside of those in the project.
- The opportunities that exist to offer benefits to the participating community and animals.

Community & guardian considerations

- Who will observe the project in action, and what the process is for ensuring that the project does not have adverse effects on the community (e.g., if community members view an animal in distress as part of the project).
- The strategy for managing differences between how those implementing a project and the community view or value dogs and cats.
- Whether there are religious, cultural, or social reasons why a project may not be considered appropriate—and, if yes, how the project will be adapted.
- How existing beliefs and attitudes about cats and dogs impact the approach of the project.
- Whether there are any individuals or groups in the community already engaged with cats and dogs and, if so, how they will be involved in the project.
- What are the best ways of engaging and informing community members about the project (e.g., printed notices, door-to-door introductions, town hall meetings, etc.).
- The community social norms or moral values that are relevant to the project, including whether the implementing team agrees with these ethics and, if not, how this divide is broached.
- What history the target community has with research, and how to best understand the community's attitudes as a first step of the project.

Endpoints

- Whether there are community-related endpoints to the project—in other words, what scenarios with individual or stakeholder group opposition would end the project.
- Whether and how the project will be continued if it is beneficial to the community.
- How the success of the project will be evaluated from a community perspective.
- How community members will obtain results in a format that is understandable and useful.

Convening an Internal Ethical Review Board and Example Form for Ethical Review

Below is a case study describing how one organization used the Ethical Review toolkit as a guide to create its own internal Ethical Review Board (ERB). Its goal was to supplement a mandated institutional ethical review and achieve a more comprehensive ethical review process for a study involving owned cats and dogs. It describes the motivation to develop an ERB, the ERB membership, reading materials, and meeting structure, and lessons learned. It also provides the questions that staff answered in advance of the first ERB meeting, which delved into core ethical issues and compelled those implementing the study to justify their decisions. Note that these questions were designed to supplement an institutional ethical review process, not as a stand-alone ethical review.

The Alliance for Contraception in Cats & Dogs (ACC&D) is working to develop a method to mark and identify animals who have been non-surgically contracepted, as well as those vaccinated against diseases such as rabies. It must be safe, humane, effective, and simple to apply in conscious free-roaming animals who were not anesthetized for their fertility control treatment. Finding a solution involves studying promising methods in awake dogs and cats.

ACC&D was ready to evaluate a microneedle tattoo in a small cohort of animals. Partnering with an academic institution necessitated undergoing an IACUC review, but ACC&D knew that the IACUC would not address key ethical issues for a pilot study that is distinctive in many ways, including applying tattoos to five pet animals in their home. Therefore, ACC&D wanted to supplement with an independent review that would focus on ethical questions not addressed in an IACUC. The ERB review took place before IACUC submission.

ACC&D therefore established an internal Ethical Review Board (ERB). This case study describes Board selection, meeting structure, and lessons learned from the inaugural ERB review. The goal is to provide a starting point for other groups that wish to create an internal ERB process for their projects.

ERB member selection was guided by the skill sets and personal qualities in Tables 1 and 2; skill sets in a traditional IACUC were also incorporated. The result was a Board of six members, five of whom have longstanding animal welfare backgrounds. Professions included veterinarians, a theriogenologist, an attorney, an animal behaviorist, scientists/researchers, and animal welfare professionals, with expertise that includes ethics and work in less-developed regions.

The Board had two meetings by conference call and one follow-up e-mail correspondence, described below.

Meeting #1:

Purpose: The ERB discussed and provided feedback on ethical concerns related to the proposed study. ACC&D reviewed and addressed these concerns in advance of the second meeting (held two weeks after the first).

Advance reading materials: Study protocol and forms (33 pages); completed ethical review questions (9 pages); a copy of this ethical decision-making guidance document and toolkits, with guidance on specific sections for focus.

Meeting structure: ACC&D staff were present to facilitate member introductions, recap goals for the ERB, and answer questions about the study and protocol. Staff then left the call, allowing the ERB to meet in confidence.

Questions for discussion: ERB members were provided with the following list of questions as a guide for discussion:

1. What, if any, questions or concerns do you have regarding the study design, protocol, partners, and funding? (If applicable, do you believe that these concerns are resolvable? Do you have any recommendations for how to address?)

2. What, if any, questions or concerns do you have regarding the welfare of animals involved in the study? (If applicable, do you believe that these concerns are resolvable? Do you have any recommendations for how to address?)
3. What, if any, questions or concerns do you have regarding the welfare of human stakeholders in the study? (If applicable, do you believe that these concerns are resolvable? Do you have any recommendations for how to address?)

What, if any, changes would you recommend to the protocol to support proceeding with the study?

Outputs: One ERB member volunteered as Secretary. She took meeting notes, circulated them to other ERB members for approval, and then sent to ACC&D staff. The notes detailed ERB members' concerns and suggestions for the study design.

Meeting #2:

Purpose: The ERB discussed changes made to the protocol following meeting #1 and noted outstanding questions and concerns.

Advance reading materials: Revised study protocol and forms (41 pages); point-by-point responses to concerns and suggestions raised in the first meeting based on notes provided by the ERB Secretary (4 pages).

Meeting structure: ERB members were asked to provide feedback on the revised protocol and forms, specifically whether the changes addressed their concerns, and/or whether any new concerns arose since the first meeting. ERB members were subsequently asked for feedback on the ERB review and meeting process and structure, and the relevance of the ethics guidance document and toolkits to their review process. ACC&D staff were present for this meeting.

Outputs: The Secretary took notes on the meeting, circulated them to other ERB members for approval, and sent them to ACC&D staff. The notes listed remaining concerns and suggestions.

Subsequent communication: Outstanding suggestions were very limited, so the ERB and ACC&D staff together decided that a third conference call was unnecessary. ACC&D staff made tweaks to the protocol and forms and developed point-by-point responses to the ERB members' suggestions; both documents were sent to the ERB for final approval by e-mail.

Learnings

The inaugural ERB process yielded learnings and ideas for improvement, which are noted below.

- How to best answer the ERB's protocol questions: There was consensus among the ERB that it is important to allow time to ask protocol-related questions of those implementing the project. In this instance, these questions took place at the beginning of the first meeting, after which ACC&D staff departed so that the ERB could have a confidential discussion. It is unclear that this is the optimal way to proceed due to the length of the discussion and some tangential dialog (see below). A potential alternative would be for the ERB to start by meeting alone, compile a list of questions, and then have those implementing the project respond to the questions during the meeting or in follow-up written form. This would need to be trialed to determine if one approach works better than the other.
- Maintaining ERB confidentiality: ACC&D sought to ensure that the ERB had sufficient time for confidential discussion. The length of time spent on questions at the beginning of the first meeting cut into time available for confidential discussion—an essential aspect of an ERB meeting to ensure that all feedback, including negative feedback, is captured. Changing the order of events in the meeting could potentially address this.
- Staying focused on core ethical questions: The ERB found that ACC&D staff's thorough responses to the ethical considerations questionnaire (provided below) addressed many of the questions they would have otherwise had regarding the ethical underpinnings of the study—a good thing!

Despite the ERB's focus on ethical issues, the expertise and experience of its members led to a number of questions and suggestions regarding non-ethics-related aspects of the proposed study. The feedback no doubt strengthened certain details in the protocol (also a good thing!), but it did lead, at times, to digressions from the main focus of the meeting.

Future planning for this likely scenario could include enforcing a focus on ethics specifically or allotting more time for discussion to accommodate feedback on topics either unrelated or tangentially related to ethics.

- ERB leadership: For the inaugural ERB meeting, a member volunteered to serve as Secretary, but no one volunteered as Chair (understandable, given that it was the first time trialing this process). As a result, ACC&D staff assumed a leadership and facilitation role during their participation in the meeting. In the debriefing session, everyone agreed that it is essential to have an ERB Chairperson, particularly to ensure a smooth meeting without the presence of those implementing the study.

  Is the ERB binding? This is a challenging question. A "binding" ERB would mean that the ERB could state that a project cannot proceed in its proposed form—or at all. It gives the ERB authority consistent with that of conventional institutional ethical review bodies. The alternative is for the ERB to have a supervisory or guidance role, but not ultimate decision-making control.

  In this particular case, the authority of the ERB was not established in advance. ACC&D was extremely deferential to ERB guidance, which was easy because the expertise of the members was highly valued. Most recommendations and requests were incorporated without question; in a handful of instances, dialog between ERB members and ACC&D staff yielded resolution about how to proceed, meaning that the authority of the ERB to approve or reject the project was never at issue. However, such an outcome is not guaranteed.

  In short, the authority of the ERB should be established in advance. In general, we would recommend that it be given authority to reject a study based on ethical grounds. However, this may not be the right decision in all instances, with possible exceptions being whether the ERB is acting as a supplement or an alternative to an institutional ethical review body (e.g., IACUC, IRB, or AWERB), and the experience and expertise of the ERB members.

- ERB recommendation and decision-making process: One question that arose during this inaugural ERB meeting is whether ERB decisions and recommendations are based on consensus or majority vote. Members had differences of opinion on multiple issues, including some that were pivotal to study design. With this particular ERB, discussion of these issues was productive, and members ended up in general agreement on how to proceed. However, this is not guaranteed. Determining what to do in instances of disagreement is essential, particularly if the ERB's recommendation is binding.

*****

ACC&D staff created the following list of questions to answer in advance of the first ERB meeting and send to ERB members as advance reading. The questions were designed to delve into core ethical issues and compel those implementing the study to justify their decisions—particularly about issues that would not be addressed as part of the IACUC review. ERB members felt that the information contained in the document was useful and saved time during the meeting that would otherwise have been spent asking why staff had made certain choices regarding the protocol.

The questions were designed with other studies and projects in mind; organizations and groups seeking to create their own ERBs are encouraged to use them.

Instructions

The following questions are designed for the Principal Investigator or alternative project lead to answer. They are intended to prompt careful consideration of the ethical decisions and implications of the project design and be reviewed in conjunction with the project protocol as part of an internal organizational ethical review process. Please answer in as much detail as possible, making references to the project protocol and forms as necessary.

Study design, protocol, partners, funding

1. What work has taken place to determine if the project is redundant, what value it is likely to add, and whether it could be improved?
2. Are the project's decision-making processes, data quality, and data management sufficiently rigorous to ensure meaningful results and learnings? Please explain.
3. Who are the partners and personnel in the study? What was the process for selecting them?
4. Could someone potentially view funding or partners for the project as presenting a conflict of interest? Why or why not? If a conflict of interest could be identified, how has it been addressed?
5. Are any ethical issues outstanding in the study protocol? Please explain why or why not.

Animal welfare considerations

1. What level of anticipated risk will the animals face from the project's start to finish? How have risks been determined, and are they justified given the anticipated benefits of the project?
2. How and why were the particular animals in the project selected? How and why were the numbers of animals in the project selected?
3. Will the project personally benefit the animals in the project? If yes, how? If no, how do you justify their participation or use in the project?
4. What steps have been taken to ensure that the animals in the project enjoy good welfare, both physically and psychologically, from the very start to very finish of the project?
5. What safeguards and endpoints are in place to ensure that animals in the project will not suffer?

Human stakeholders

1. Who are all the stakeholders in the project? (If the community is impacted in any way, please delineate who/what comprises the community.)
2. What has been done to engage each stakeholder group? What is the evidence that each stakeholder group is engaged in and supportive of the project? Are there any competing interests among stakeholders and, if so, how have they been addressed?
3. What has been done to ensure that informed consent has been received for any human participation in the project, and informed permission for any animal participation? Were there any challenges to gaining informed consent/permission and, if so, how were they addressed?
4. Are there any aspects of human stakeholder engagement that require consideration? If no, why not? If yes, what are they and what has been done?

References

Note any academic or online references cited in answers to the above questions.

Please contact info@acc-d.org with any questions about details of the ERB or if you would like to view materials submitted as part of the process. If your organization starts its own ERB, please let us know—we want to hear about it!

EXAMPLE FORM FOR INDEPENDENT ETHICAL REVIEW

of Project Monitoring, Evaluation, and Impact Assessment

If you or your organization is in a position to conduct an ethical review, whether in addition to or instead of an institutional ethical review, a key component will be completion of written forms. We invite you to use or adapt the example forms in this publication, as appropriate. Institutional ethical review forms can also be found online.

The form shown on the next pages was adapted by Dr. Lou Tasker and Dr. Elly Hiby from work involving owner questionnaires and street dog surveys that required submission to an independent ethical review body. It follows part of a required format for an academic institutional review board in the UK. As such, it is a much more comprehensive, standardized set of questions than those provided as part of the independent ethical review case study on p. X, which was conducted as a supplement to institutional ethical review.

- The form outlines ethical considerations relating to research for monitoring, evaluation, and impact assessment for projects, not the project itself (e.g., spay/neuter, community animal health clinics) – it is not intended to be prescriptive or exhaustive, as each situation is different!
- The form does not replace required review board formats at host institutions or in the countries where you work, but it can be used as an example of the types of information mandated review boards may require, and the ethical considerations of undertaking independent research that underpins evidence-based monitoring, evaluation, and impact assessment for dog population management interventions.
- The form is divided into sections:
    1. The first section provides you with an opportunity to outline the project to the review board: Why are you carrying out the project? Is the design if the project "fit-for-purpose"? Will it provide reliable information to help with understanding the impacts of the intervention?
    2. The next sections ask a series of questions to ascertain what harms may be incurred by humans or animals during the course of the project, and what steps you have taken to avoid or mitigate those harms.
    3. The final sections give you an opportunity to provide copies of the informed consent dialog, what will be included in a questionnaire, and the detailed method for dog street surveys.

Please contact info@acc-d.org with any feedback on your experiences of ethical review for independent research.

EXAMPLE SUBMISSION FORM FOR INDEPENDENT ETHICAL REVIEW/ Tasker et al, Example independent ethical review form for field innovations or interventions.

1. APPLICANT DETAILS

Name, address, contact details:	
Affiliation: *If different from above.*	
Organisation(s) involved, contact details	
Project funders:	
Project start date:	**Project end date:**
Short project description: *Briefly explain (500-1000 words) the purpose (aims and objectives) and justification of the project, including why you need to do the study, how you intend to undertake the work, and what you intend to do with the information you have gathered. Explain whether this work is baseline (pre-intervention), ongoing monitoring and evaluation, or end-of-project evaluation/impact assessment.*	

Form Page 1

1

2. RESEARCHER SAFETY

Does the proposed research pose any particular risks to the researcher(s)? *Potential risks to consider include: working in a dangerous or isolated geographical area; lone working; working with equipment and manual handling; environmental hazards; chemical and biological hazards; and emotional risks associated with sensitive research.*	YES/NO
If 'Yes', use this box to provide information on the risks you have identified and the steps taken to avoid or reduce these risks.	

3. RESEARCH INVOLVING OR IMPACTING ANIMALS

Does your research project involve animals in anyway?	YES/NO
State here what the research method involves in relation to its impact on animals. Can the methods you use cause pain, distress (including fear), distress or lasting harm to animals – directly or indirectly? If you answer "yes," state all the potential harms to animals and what you will do to reduce or avoid them.	

4. DATA PROTECTION, COPYRIGHT AND OTHER CONSIDERATIONS

Does the proposed research involve accessing records of personal or confidential information?	YES/NO
If 'Yes', state what type and source of information is required.	
Does the proposed research involve the recording or use of audio-visual material for which consent is required?	YES/NO
If 'Yes', state what method and how consent will be obtained.	
Does the proposed research involve the remote acquisition of data from or about human participants using the internet and its associated technologies?	YES/NO
If 'Yes', state what data and the process of acquisition etc.	
Does the proposed research involve accessing potentially sensitive data through third parties?	YES/NO
If 'Yes', state what data, from whom and how the data will be acquired	
Does the proposed research involve reproducing copyrighted work in published form?	YES/NO
If 'Yes', state the type and source of information, and how the necessary permissions will be obtained.	
Does the proposed work involve activities which could temporarily or permanently damage or disturb the environment, or archaeological remains and artefacts?	YES/NO
If 'Yes', state the risks, the permissions required to undertake the work, and how risks will be avoided or mitigated.	
Does the proposed work involve a potential conflict of interest or raise ethical issues regarding the source of funding or where publication of research data may be restricted?	YES/NO
If 'Yes', state what those conflicts of interests are.	
Will the participants' data be stored on a computer?	YES/NO
If Yes, include further information in **Section 9 RESEARCH METHODS, Data recording**	
Are there mandated requirements for protection of data in the host country or in countries you may share data with (e.g., if you collaborate with individuals from more than one country)?	YES/NO
If 'Yes', state what those requirements are.	
Will you share data with other individuals in different countries?	YES/NO
If 'Yes', state which countries, and how you will ensure all parties will adhere to the relevant data protection legislation.	

5. RESEARCH INVOLVING HUMAN PARTICIPANTS

Does the project involve living participants?	YES/NO
If 'Yes' briefly state how you have selected participants.	
Does the proposed research involve interviews with participants or the use of questionnaires?	YES/NO
If 'Yes' state which (e.g. doorstep questionnaires).	

Form Page 2

Will any of the participants be in a dependent relationship with the funders or study investigators? (e.g. personal or professional relationship including consultancy, in receipt of funding or likely to apply to the organisation for funding in the future?)	YES/NO
If 'Yes' state the nature of the relationship, and how this may affect the project (e.g., design, conduct and reporting).	
Will inducements (other than reasonable expenses and compensation for time) be offered to participants?	YES/NO
If 'Yes' state the inducements.	
Does the study involve participants who are particularly vulnerable or unable to give informed consent? (e.g., people under 18 years of age, people with learning disabilities, participants where their first language may be different to that of the host country?)	YES/NO
If 'Yes' explain how you will meet the criteria of informed consent (e.g. by using a proxy or an interpreter)	
Does the study involve participants located outside of the country in which the ethical review process is being conducted?	YES/NO
If 'Yes' explain how the review process takes into account potential harms on humans, animals and stakeholders at the local level.	
Will the study involve discussion of sensitive topics (e.g., sexual activity, drug use, experience of violence, abuse or exploitation, their mental health, gender or ethnic status, criminal activity)?	YES/NO
If 'Yes' state which sensitive topics, and if their responses will be voluntary, anonymised and kept confidential.	
Are there issues of safety for the participants?	YES/NO
If 'Yes' outline what they may be, and how you have avoided or reduced risks to participants.	
Is there any realistic risk of any participants experiencing either physical or psychological distress, humiliation or discomfort (beyond the risks encountered in normal life)?	YES/NO
If 'Yes' state what they are, and what safety net you have put in place for support during and after their participation in the project.	
Are there any other potential hazards?	YES/NO
If 'Yes' list and include steps to address them.	
If research is observational, will you ask participants for their consent to being observed?	YES/NO
Will your project involve deliberately misleading participants in any way?	YES/NO
Will participants be informed of the nature and purpose of the study?	YES/NO
This should be detailed in your informed consent dialogue, information and debriefing sheets provided in **Section 11 APPENDIX.**	
Will they be given a written information sheet or letter?	YES/NO
If 'Yes' provide a copy in the relevant **Section 11 APPENDIX**.	
Will you tell participants that their participation is voluntary and that they may withdraw at any stage and for any reason?	YES/NO
This should be detailed in your informed consent dialogue, information and debriefing sheets provided in **Section 11 APPENDIX.**	
With questionnaires or structured interviews will you give participants the option of omitting questions they do not want to answer or terminate the interview at any time and for any reason?	YES/NO
This should be detailed in your informed consent dialogue, information and debriefing sheets provided in **Section 11 APPENDIX.**	
Will you obtain written consent for participation?	YES/NO
A copy of the written consent forms or verbal consent dialogue should be provided in **Section 11 APPENDIX.**	
Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	YES/NO
If 'No', explain why. If 'Yes' you should explain how you will meet this obligation in **Section 9 RESEARCH METHODS, Data recording**	
Will you gain additional consent, and include extra measures for audio recording of interviews?	YES/NO
If 'No', explain why. If 'Yes' you should explain how you will meet this obligation in **Section 9 RESEARCH METHODS, Data recording**	
Will you debrief participants at the end of their participation?	YES/NO
If 'No', explain why. If 'Yes' you should explain how you will meet this obligation in **Section 9 RESEARCH METHODS, Data recording**	

Form Page 3

6. WIDER STAKEHOLDERS

Have you identified and engaged with local stakeholders (e.g. local community groups, local authorities, local veterinarians, etc.)?	YES/NO
If 'No' explain why not. If 'Yes' outline who the stakeholders are, their interests in the project, and whether they are aware of the project.	
Does the proposed research pose a risk to wider, local stakeholders?	YES/NO
If 'Yes' list the risks to each stakeholder and outline how you have mitigated them.	
Does the proposed research affect the design and timing of the intervention?	YES/NO
If 'Yes' state how the design and timing of the intervention may be affected.	
Are the local stakeholders aware that the timescale and design of the intervention may change with the research you are undertaking?	YES/NO
If 'No' explain why not.	

7. DATA COLLECTORS

Will you be using staff or volunteers to collect the data?	YES/NO
If 'Yes' briefly explain how you will recruit and check competencies of staff or volunteers.	
Will staff or volunteers be trained in the data collection methods?	YES/NO
If 'No' explain why not. If 'Yes' state briefly how staff or volunteers will be trained.	
Will staff or volunteers be given training on the ethical considerations of this project (e.g. how the design and conduct or the project aims to reduce risks to animals and humans etc.)?	YES/NO
If 'No' explain why not. If 'Yes' state briefly how staff or volunteers will be trained.	

8. ETHICAL CONDUCT

State what guidelines you will be adhering to – e.g., 'The project will be conducted in-line with the following guidelines [state name of guidelines}, respecting the rights and dignity of participants, and the legitimate interests of funders, stakeholders and collaborators.

9. RESEARCH METHODS

Use this section to provide more detailed information on the methods you will be using.

9.1 Data recording, analysis, storage, protection, sharing and management

State how the data will be gathered, processed, stored (e.g. in electronic or paper form), secured, shared and reported (will the final report be open access or confidential – who will be able to see the report?).

10. REFERENCES

Form Page 4

11. APPENDIX

11.1. Copy of doorstep questionnaire
[INSERT COPY]
11.2. Examples of information, consent, and debriefing sheets for participants
• *Include examples of any information sheets you intend to give participants.* • *Include the consent dialogue you will have with participants on the doorstep.* • *Include how you will document informed consent from participants.* [INSERT COPIES]
11.3. Detailed method for dog street surveys
[INSERT METHOD HERE]

Form Page 5


BACK

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- Susan Getty, Project Manager, Alliance for Contraception in Cats & Dogs, U.S.
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ABOUT ACC&D

The Alliance for Contraception in Cats & Dogs (ACC&D) was founded to advance non-surgical sterilants and contraceptives for cats and dogs and to promote their global accessibility. However, this resource is designed for much broader use: mass vaccination campaigns, animal birth control initiatives, Trap-Neuter-Return projects, clinical studies, or any project or research that involves animals outside of a laboratory setting.

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